PRICE
PER COPY
₹25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/TECH/WPP-337/WEST/2021-23
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 22 (PAGES: 44) | 08 TO 14 JUNE 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

CRAFTSMANSHIP

BEYOND COMPARE. IT'S WHAT WE ARE KNOWN FOR.

Dear Partner,

Providing our customers with the highest quality products means having a great design understanding, for a variety of applications. Thankfully, we do, with the backing of partners like Hanns G Werner GmbH+ Co. KG.

As the leading manufacturers of exceptionally high-quality neutral sugar pellets used as drug-free cores for sustained release formulations, Hanns G Werner GmbH+ Co. KG is well-regarded for their stringent quality control, cutting-edge technology, ever-evolving research and innovation.

Signet-ure craftsmanship

pharm-a-spheres™

Particle Size Range *(Mesh ASTM)*	Diameter *(in microns)*
170-100	150-90
80-100	180-150
70-80	212-180
60-70	250-212
50-60	300-250
40-60	425-250
40-50	425-300
40-45	425-355
35-40	500-425
30-35	600-500
25-30	710-600
20-25	850-710
18-20	1000-850
16-20	1180-850
16-18	1180-1000
14-16	1400-1180
12-14	1700-1400
10-12	2000-1700

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 22** **08 to 14 June 2022**

IDMA ACTIVITIES:

CCI MATTERS:

DGFT MATTERS:

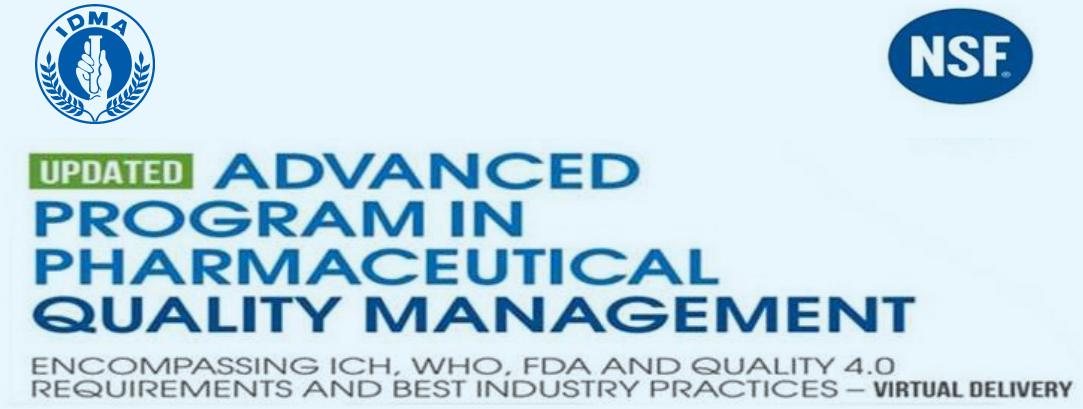
CUSTOMS MATTERS:

PARLIAMENT NEWS:

MoEF&CC MATTERS:

INTERVIEW:

NATIONAL NEWS:



3rd June 2022

Dear Member,

APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

For companies who want to grow their business in Europe & the US.

APPQM+ Series 3 Commences July 2022

Why APPQM in INDIA?

We live in a world of 'Brutal Disruption'. Covid pandemic – what next? **Prosperity awaits those who do the basics to PhD level.**

When launching the first series of the APPQM, we at IDMA along with NSF Health Sciences, UK boldly stated that APPQM, the unique, World-Class education program will just do that and ***Develop Change Agents For Quality Excellence.***

Well, Series One & Two lived up to the expectations of the industry. Over 40 delegates attended Series One & 28 delegates attended Series Two.

Both the series were a resounding success and this is what the delegates thought:

- ✓ Transformative
- ✓ World-class
- ✓ Best business investment we've ever made
- ✓ Worth every penny and more
- ✓ Has helped transform our quality culture
- ✓ Educating oneself while Educating others
- ✓ The course was really pragmatic and foundational in understanding the core Quality Systems framework

'Work Placement Projects' have been completed by APPQM delegates. These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

APPQM+ Series 3

Based on the success of Series 1 & 2, we are pleased to announce the launch of APPQM+ Series 3 that is expected to commence in July 2022 and covers special sessions on Digitization.

Please refer to the enclosed brochure and the video link for details of the Program covering:

- ✓ Challenges Facing the Pharmaceutical Industry
- ✓ How APPQM can help
- ✓ Benefits of the Program
- ✓ Course Format
- ✓ Details of Key Topics of the 5 Course Modules and the List of Tutors

Additional Benefits:

This virtual education program offers the following additional benefits.

- ➢ Safety of Individuals during this COVID-19 pandemic.
- ➢ Reduction in Course Fees (from £8000 for Physical Class to £3300 for Virtual Class)
- ➢ Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Please don't get left behind and register for the third series of APPQM to have a competitive edge in the global market and to be future ready.

Registration Fee for APPQM+ Series 3

The Registration Fee for APPQM+ Series 3 is Rs.4,00,000/- (Rupees Four Lakh Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the enclosed Registration Form and send it to

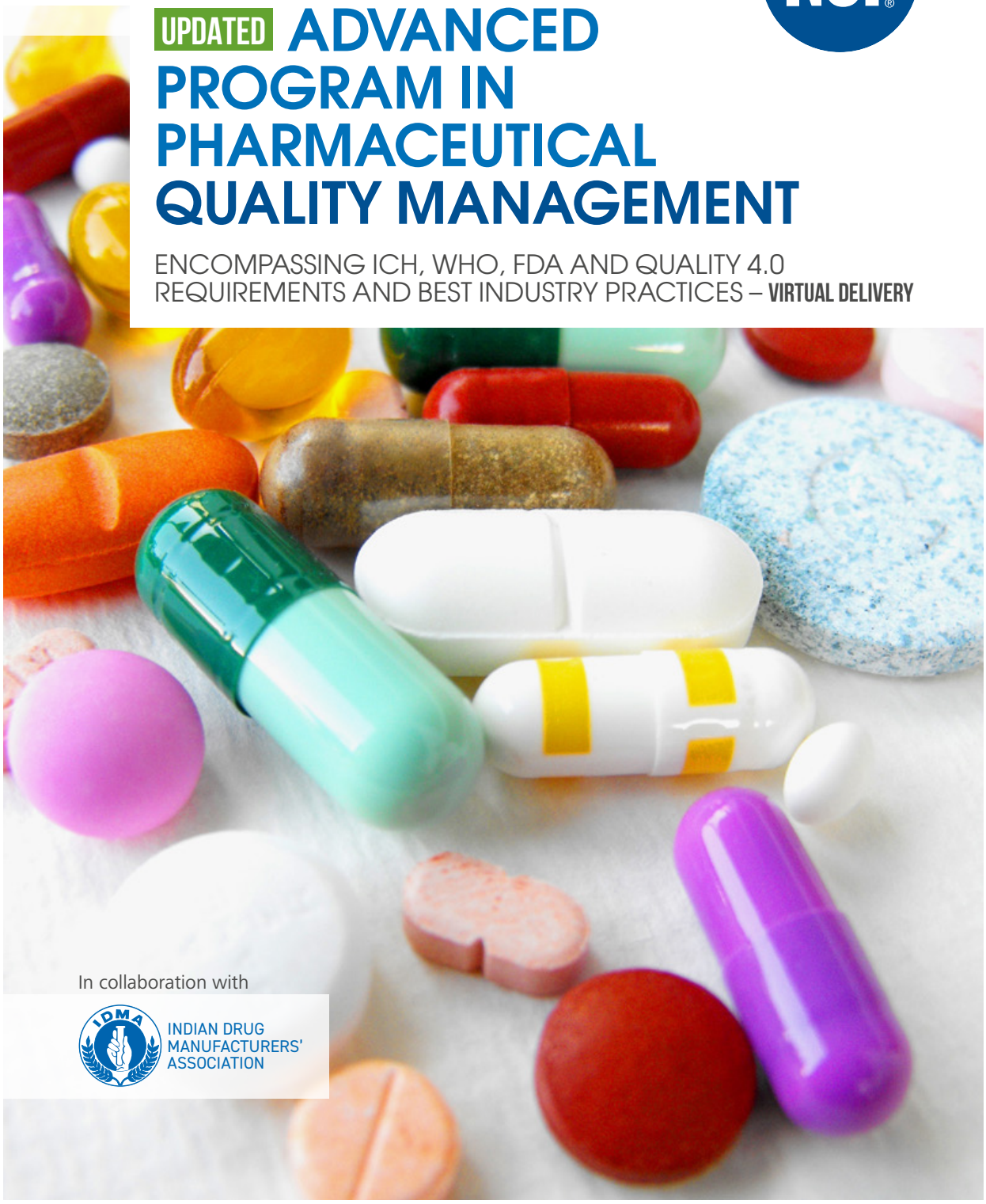
Melvin actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

For further information / queries :
You may also contact Mr. S. M. Mudda
@ mudda.someshwar@gmail.com / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M Mudda Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**Dr. Viranchi Shah** National President, IDMA	**Mehul Shah** Hon. General Secretary IDMA	**Daara B Patel** Secretary – General, IDMA


NSF
UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT
ENCOMPASSING ICH, WHO, FDA AND QUALITY 4.0 REQUIREMENTS AND BEST INDUSTRY PRACTICES – VIRTUAL DELIVERY
In collaboration with
IDMA
INDIAN DRUG MANUFACTURERS' ASSOCIATION

FOR COMPANIES WHO WANT TO GROW THEIR BUSINESS IN EUROPE AND THE U.S.

For companies who want to grow their business in Europe and the U.S.

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

India is the world's third largest pharmaceutical generics producer with the highest number of FDA and MHRA GMP-approved manufacturing plants outside the U.S. and Europe. The challenge of remaining in GMP compliance continues to be the main concern. India has seen a resurgence of breach of data integrity and quality issues. Regulatory requirements continue to become more stringent and rigorous.

Technical and QA professionals in India are trained in GMP compliance mainly through experience and need a formal education in pharmaceutical quality management of international standards.

- Sixty-four percent of companies say a shortage of skilled staff is curtailing their growth (Deloitte).
- 'There is an urgent need for more effective training, coaching and mentoring to remove fear and empower.' (Dr. Azaj Hussain, former U.S. FDA Deputy Director of the Office of Pharmaceutical Science)
- We live in a world of 'brutal disruption'. The pandemic – what next? The regulatory landscape will continue to change, and prosperity awaits those who can do the basics to Ph.D. level.

HOW THIS TRAINING CAN HELP

This unique, world-class program will provide the training needed to comply with GMP regulations. Course modules are very interactive and led by world-class, international experts. You will learn best-in-class practices and apply them in practical problem-solving and real-life case studies. You will learn by doing.

In addition to module-specific content, you will be provided with a deep understanding of simplification, risk-based decision making and advanced problem-solving skills. You will receive practical instruction on the leadership and communication skills required to add value to your organisation and to successfully interact with regulatory agencies in the U.S. and EU and other key stakeholders.

WHY CHOOSE NSF?

NSF's Advanced Program in Pharmaceutical Quality Management is taught by world leaders in PQM. Based in the UK, NSF have a global reputation for excellence in PQM. Our course tutors have a minimum of 30 years' global, hands-on industry experience. Many are former MHRA inspectors. All have profound knowledge of PQM and some have authored ICH and WHO guidance documents.

NSF has trained regulators from eight regulatory agencies including those in the EU and USA. Respected by regulatory agency and industry associations, NSF has excellent relationships with IDMA, ISPE, PDA organisations and U.S. FDA, WHO and EU regulatory authorities.

With offices in Delhi, NSF has an excellent understanding of Indian culture and the Indian pharma industry, gained over the last 30 years.

BENEFITS OF THIS TRAINING

From attending this program, you will gain the skills and knowledge to help your company improve business performance and regulatory compliance. Clients who have attended NSF programs have generated $ millions in savings.

For example by:

- Reducing repeat deviations by 78 percent
- Reducing 'human error' deviations by 67 percent
- Achieving 99 percent 'right first time' at product release
- Using risk-based decision making to simplify processes and systems, and to focus resources
- Achieving zero regulatory observations following an audit

Attendees will also:

- Change how they think. NSF courses are designed to change behaviours, not just provide knowledge. Participants will be able to transfer the learning into their workplace
- Learn best industry practices in PQM so that their companies can compete with the best
- Gain an in-depth understanding of the critical aspects of PQM (see Course Modules)
- Leave with the knowledge required to help protect their company's legacy, reputation and future

COURSE FORMAT

The program is presented in five modules, each comprising four days, over a 10-month period. Training takes place using virtual instructor led training via Zoom. Attendees at the second series which was delivered virtually were impressed with how easy it was to interact with other participants and how the course was specifically developed with virtual breakout rooms and information using the NSF Learning Management System. You will receive:

- A minimum of two tutors per module, to ensure a good tutor-to-delegate ratio
- An intensive, distraction-free and highly interactive learning environment using real-life case studies and problem solving exercises
- A work-based project to complete

▶▶

MODULE FOUR: Data Analysis for Business Improvement

Tutors: **Dr P. Gough and Dr D. Young**

- Summarising and visualising data (histograms, probability curves and box plots)
- Confidence in your means and proportions
- Statistical process control
  - Control charts
  - Fishbone diagrams and Pareto charts
  - Process capability
  - Six Sigma
  - Statistical testing
  - T-test
  - ANOVA
  - Outliers
- Regression analysis
- Design of experiments
- Multivariate analysis

MODULE FIVE: Quality by Design, Process Validation and Technology Transfer

Tutors: **Mrs Emma Ewins and Mr Richard Kettlewell**

- Quality by Design (QbD): ICH Q 8, 9, 10 and 11
- Modern approach to process validation
- Process design
- Application of quality risk management to process validation
- Tools for process validation implementation
- Equipment and utilities qualification
- Applying statistics for process validation
- Process performance qualification (PPQ) – How many batches?
- Process validation strategy and planning
- Ongoing/continued process verification
- Packaging validation
- Technology transfer
- Laboratory electronic data management
- Computer systems validation

NEXT STEPS YOUR CALL TO ACTION

If you would like more information on this unique opportunity, please:

- View a video of past participants on this course, click **here**
- Contact IDMA at: **actadm@idmaindia.com** or **technical@idmaindia.com**
- Contact NSF at: **pharmamail@nsf.org**

- **S. M. Mudda**
  Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM
- **Dr Viranchi Shah**
  National President, IDMA
- **LynneByers**
  Global Managing Director, Pharmaceutical Consulting, NSF Health Sciences

NSF INTERNATIONAL

www.nsf.org | www.nsf.org/locations LinkedIn

COURSE MODULES

Some of the key topics covered in each module are provided below.

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

Tutors: **Mr Rob Hughes and Mr S. Mudda**

- How to ensure your PQS is regulatory compliant, improves your competitive edge and drives business improvements
- Integration of quality systems across the product lifecycle (quality systems approach for cGMP implementation, from philosophy to practice)
- Making use of risk information to drive improvements (risk-based decision making)
- Senior management roles and responsibilities for the PQS – who must do what
- The essentials of data integrity
- Best practices in designing an electronic PQS
- Integration of Industry 4.0 into the design of the PQS
- The art and science of simplification
- Batch release system: How to achieve 100 percent 'right first time'
- How to become stronger and better following complaints and recalls
- Product quality reviews: How to use data and knowledge to drive improvement
- Management review of quality systems and the use of quality metrics (measuring only what matters)
- Continuous quality improvement and the cost of poor quality

MODULE TWO: Managing Change; Change Control and Deviations

Tutors: **Mr Rob Hughes, Mr S. Mudda and Ms R. Carmichael**

- Change control: How to use your system to:
  - Stop unnecessary change to ensure resources are focused on changes that only add value
  - Approve changes in minutes, not hours or days
  - Improve successful implementation of approved changes
  - Make change control fast and efficient
- CAPA management
- Investigation and report writing skills
- Deviation management: How to ensure your system:
  - Prevents repeat deviation incidents
  - Is simple, fast and effective
- Data Integrity:
  - Data Integrity principles and how to implement them effectively
  - Understanding data lifecycle

MODULE THREE: Human Factors – Getting People to Follow the Rules

Tutors: **Mr Rob Hughes and Mr S. Mudda**

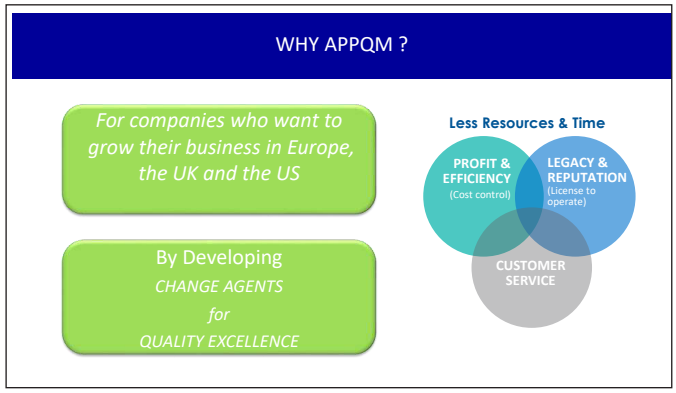
- Human error: Causes and prevention
- Behavioural GMP: How to improve behaviours in the workplace
- How to get the best from your people and keep them
- Train vs. educate: How to build second-level leadership for quality management
- Making your quality organisation fit for purpose, whether centralised, decentralised or site managed
- How to overcome pitfalls in remediation programs and integrate them within the PQS
- Fostering a culture of quality (how to identify the relationship between company quality performance and prevailing quality culture and make quality normal, easy and rewarding)

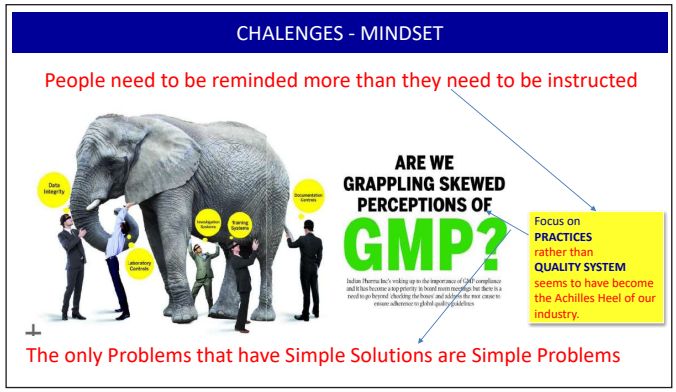
▶▶

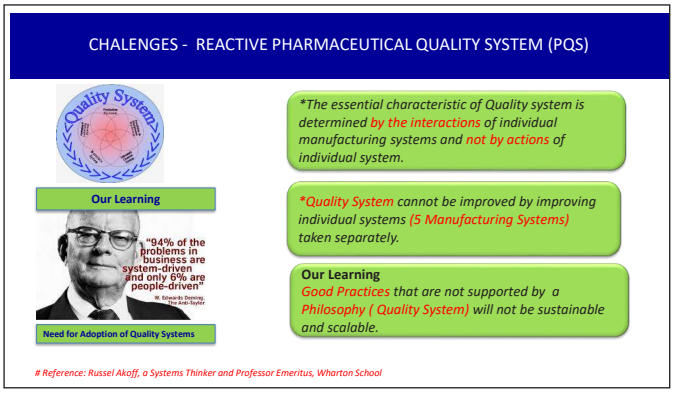
PRESENTATION

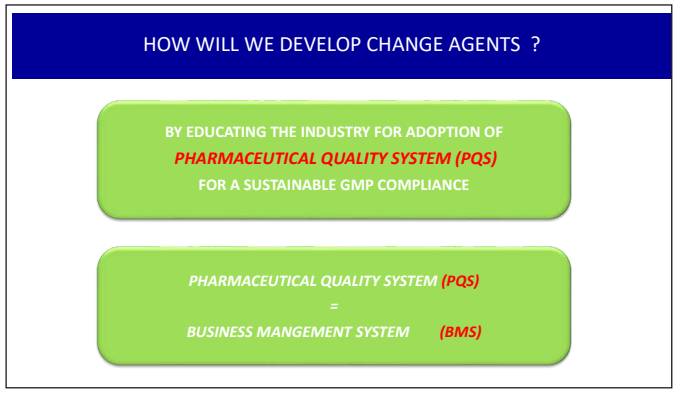
Launch of APPQM Series 3

Mr S M Mudda, Program Director & Chairman Regulatory Affair Committee, IDMA









APPQM IS DESIGNED FOR INDIAN COMPANIES

APPQM is adopted from highly successful Quality Management Program of NSF UK.

The contents are selected by experts keeping in mind challenges faced by India Pharma*

- *NSF is the global leader in providing 'Qualified Person'(QP) training across the EU.The expert faculty include ex-regulators (MHRA) and*
- *Seasoned professionals with 35 years plus hands on experience .*

**Mr. S.M.Mudda*
Chairman, Regulatory Affairs, IDMA and a strong Proponent of Quality Systems

**Mr. Martin Lush*
Ex- Global VP, NSF International, UK and a leading consultant & tutor

**Dr. Ajaz Hussain*
Ex-Deputy Director US FDA , Educationist, Advisor and Mentor

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

APPQM is
Not a TRAINING PROGRAM
but
An EDUCATION PROGRAM in PQS
Focussed on 21st century Leadership Development of QA , QC, Manufacturing and R&D professionals

APPQM- Program Modules

- Pharmaceutical Quality Management Systems – Best Industry Practices *(How to ensure your QMS drives business improvements)*
- Managing Change; Change Control and Deviations *(Advanced problem solving, deviation management, report writing and change management)*
- Human Factors–Getting people to follow the rules *(How to improve performance, reduce human error, embed a quality mind-set & keep your people)*
- Transforming Data into Information – the Practical Application of Statistics to Transform your Business *(The practical application of statistics to transform your business)*
- Quality by Design, Process Validation and Technology Transfer *(Building a foundation for Product Quality and Knowledge Management)*

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

OUR DAY AT THE PLACE OF WORK WILL NEVER BE THE SAME

This is what they thought after a year of implmenatation of APPQM Learnings:

Transformative and Life Changing.

It is highly recommended for anyone who wants to challenge the status quo (at work) but doesn't know how.

Decision making has become more efficient and so the inter-personal relationship.

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

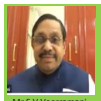
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES


APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


APPQM will help develop future quality leaders
Dr. B Suresh, Pro-Chancellor, JSS University

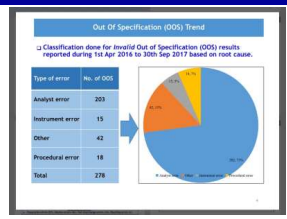

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


Inclusion of Digitization topics will enhance the next series of APPQM
Mr Mehul Shah MD, Encube Ethicals &Hon. General Secretary, IDMA

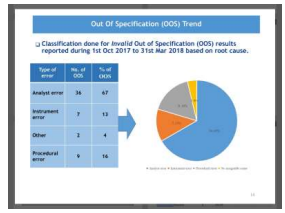

IDMA should aim at developing 1000 Change Agents for quality excellence in coming years
Mr S V Veerramani, MD, Fourrts India


APPQM will help to remain competitive even while complying with the regulations
Dr George Patani ,VP (Western Region), IDMA

Benefits of APPQM –ROI



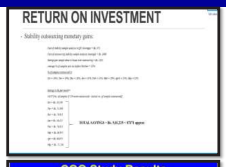
BEFORE

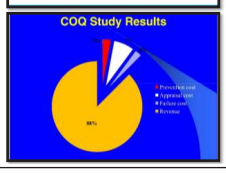


AFTER

TOTAL SAVING OF Rs. 5 Cr.

Benefits of APPQM -ROI





Acknowledgments

S.V. Veerramani — Past National President, IDMA for mentoring this program & providing his unstinted support.

Mahesh Doshi — Immediate Past National President, IDMA for his continued support

Sudhanshu Pandey, — Joint Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India, for his support

S. M. Mudda — Chairman, Regulatory Affairs, IDMA and Program Director, APPQM for his Vision & Innovation and for his unstinted support & active participation in conducting this World Class program

Dsara B Patel — Secretory General IDMA for his continual support, active participation and coordination success of APPQM

R.S.Iyer — Renowned Quality Guru and our Inspiration "Quality of Work Determines The Quality Of Products"

THANK YOU FOR YOUR ATTENTION

CHANGES IN THE NATURE OF PHARMACEUTICAL R&D PROGRAMS

Dr. George Patani, *Associate Editor, Indian Drugs*

Dear Reader,

The global innovation index 2021 ranked INDIA 48th among 131 countries. This low ranking assigned to India reflects the quality of our research programs. In the realm of pharmaceuticals, the Indian industry has excelled in the manufacture of low value generic products, however we are yet to demonstrate our capability to manufacture newer, innovative and advanced products such as biologicals, complex generics and higher value device based drug systems.

As we approach the end of the financial year, it is important that we review the quality and the progress of our research programs. We currently use various parameters to evaluate the success of our research programs which include the number of publications, the quality of the publications usually measured through various journal metrics, the number of research patents/ grants obtained and the number of industrial projects in hand. In addition to these parameters, in industrial R&Ds the number of products commercialized is often considered as the most important and useful metric of the success of the R&D program. However, on further introspection, we observe that most of the projects pursued in Indian R&Ds are incremental projects and not really focused to the adoption of new technologies and innovation. A study of the revenue potential of each of the projects may also be a good metric to evaluate the quality of projects in an R&D program.

A note-worthy consequence of the COVID-19 pandemic has been a change in the risk appetite and the nature of the R&D programs of a number of corporations. A more "Can Do" attitude has set in due to the support received from the various government evaluating agencies. The success of Indian healthcare companies in quickly developing and commercializing products (eg. Vaccines and diagnostic kits during the COVID-19 pandemic) has reinforced the confidence of a large number of companies of their ability to overcome the regulatory pathways and launch their products successfully within a reasonable time frame.

The COVID-19 pandemic also brought to the forefront the need to launch products in record time and forced

Dr George Patani, *is a Pharmacist from the College of Pharmaceutical Sciences, Manipal. He completed his Masters in Medicinal Chemistry and Ph.D. in Drug Delivery from the Rutgers, The State University of New Jersey. He has approx. 22 years' experience at the INGA group of companies (namely Inga Laboratories P. Ltd and Inga Pharmaceuticals), developing and manufacturing phytochemical APIs and finished dose formulations. This experience has included an extensive record of project leadership in pharmaceutical formulation development and regulatory affairs. He has authored a number of scientific publications and book chapters with over a 1000+ citations from individual manuscripts.*

Dr Patani is currently the Vice-President (Western Region) of the Indian Drug Manufacturers' Association 2022-till date. He was previously the Hon. Gen Secretary 2020-2021, Hon. Treasurer of IDMA 2017-2019, Chairman of IDMA's publication committee since 2012 and Chairman of IDMA's Industry Institute Interaction Committee from 2014 to 2019. He has been a recipient of the Outstanding Alumnus Award 2016 and Distinguished Alumnus Award 2005 from Manipal University. He has served on various committees such as the Crude Drugs and Herbal Products Committee of the Indian Pharmacopoeial Commission and the Reach Monitoring Committee of the TIFAC CORE in genomics at Manipal Academy of Higher Education etc.

various R&D teams to work together. This emphasized another aspect that we lack in Indian R&Ds, namely our ability to collaborate together in the interest of commercializing products quickly. It also highlighted the importance of building relationships within our R&D teams and also with scientists in programs of other scientific disciplines. No one discipline or scientific approach tells us the whole story. The ability to combine at least two disciplines would possibly make it easier and increase the probability of success in developing transformative therapies for various diseases.

I wish all our readers great success in their R&D programs in the New Financial Year.

Courtesy: Indian Drugs, Editorial, 59 (03), March 2022

● ● ●

A Report on IDMA & Aptar Pharma Webinar on Container Closure Systems Testing: Leak Detection and Extractable/ Leachable Studies in An Age of Complex Drug Formulations

IDMA & APTAR Pharma organized a Webinar on "Container closure systems testing: Leak detection and extractable/ leachable studies in an age of complex drug formulations" on Thursday, 26th May 2022 at 5:00 pm to 6:30 pm. Webinar was successful with the active participation of 125 plus members and excellent & elaborate addresses by the speakers.

Mr. S.R Vaidya, Chairman, MSME Committee, IDMA welcomed all the speakers and participants (as reproduced below). Speakers Mr. Patrick Daylon Pat Dayton, Project Manager of the Container Closure Integrity Testing Program at Gateway Analytical and Mr. Scott Toth, Laboratory Manager, Next Breath made an excellent presentation on "Container closure systems testing: Leak detection and extractable/ leachable studies in an age of complex drug formulations" at the webinar (as reproduced below).

The Moderator of the webinar was Dr. Prasant Bodhe, Principal Consultant CliniSearch. Ms Sapna Patil, Deputy Secretary – General, IDMA proposed the Vote of thanks (as reproduced below).

Welcome Address by Mr S R Vaidya, Chairman, MSME Committee, IDMA

Greetings from Indian Drug Manufacturers' Association (IDMA) and Aptar Pharma.

It gives me great pleasure to address this august gathering & on behalf of our National President, Dr. Viranchi Shah, Mr. Daara B Patel, Secretary General of IDMA & Mr. Kanwal Tikoo of Aptar Pharma, I welcome you all to this interesting & informative webinar titled 'Container closure systems testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations'

When Pharmaceutical companies around the world want to develop safe, efficient and compliant medicines, they turn to Aptar Pharma, the go-to drug delivery expert, for proven and complete drug delivery solutions and services.

Extractable and leachable (E/L) studies are critical to the identification and quantification of potentially harmful leachable impurities which could migrate from pharmaceutical container closure systems, medical devices, medical device packaging, and process equipment and packaging to contaminate pharmaceutical products.

This can pose a risk to the health of the patient and cause significant quality issues. A profile of extractable components must be obtained, via Controlled Extractable Studies (CES), in order to identify potential sources of leachable, such as antioxidants, plasticizers, dyes and metal catalysts, and polymer and degradation products.

Aptar Pharma is a global leader in drug delivery, consumer product dispensing and active material science solutions, they use insights, design, engineering and science to create dosing, dispensing and protective packaging technologies for the world's leading brands.

Indian Drug Manufacturers' Association (IDMA) has successfully completed 60 glorious years of its existence, providing support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located pan India.

For today's webinar, we have got two excellent speakers from Aptar Pharma - Mr. Scott Toth. Mr. Scott is the Laboratory Manager, Next breath Baltimore an Aptar Pharma Company.

His work focuses on managing the LC and spray characterization laboratories, as well as designing and executing extractables/leachables studies utilizing LC/GC/MS instrumentation. Prior to joining the team in 2021, he spent 7 years at Alcami Corporation in Wilmington, NC, developing and validating LC/GC/MS methods in support of small molecule and extractables/leachables analyses. Scott earned his Bachelor's Degree in Chemistry from Benedictine University and his PhD in Analytical Chemistry from Purdue University. In his free time, he enjoys tinkering with 3d printing, photography, various electronics, and enjoys sous vide cooking.

And Mr. Patrick Dayton, he is the Project Manager of the Container Closure Integrity Testing Program at Gateway Analytical. He is responsible for managing all CCIT day-to day operations within the laboratory as well as all customer communications and interactions for the program. Prior to joining the team in the fall of 2020, Pat has spent the past 11 years performing various pharmaceutical work, including spending 5 years at Gateway's sister company, Next Breath, developing and validating HPLC methods for nasal spray/ inhalation products. Pat earned a Bachelor's Degree in Chemistry from West Virginia University.

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we will Learn about the benefits of active packaging in challenging environments.

Thank you & once again Welcome to you all

I am thankful to Dr Prashant Bodhe who is the Principal Consultant CliniSearch for agreeing to assist us at this important webinar.

Dr. Prashant is a Pharmacologist with a vast 33+ years of experience in **Complex Generics, Bioavailability, Bioequivalence Studies; Pharmacokinetics; Global Clinical Research (Phase I-III)** & Pharmacovigilance; Regulatory Affairs; Quality Compliance and Systems; Medical and Regulatory writing, API, **Toxicology; Hazard Risk Assessment**, Liposome Technology.

He has conducted several Audits, Monitoring, Pre-inspection Preparation for BABE studies, CROs, API.

He has an extensive experience of Regulatory Affairs & Clinical Trials in both NCE & Generic products and is well versed with Global Quality Standards and Regulatory environment for conducting Phase I, II, III and IV Clinical studies, with hands on experience of all departments like Site ID, Feasibility,Study Start up, Clinical Operations, Regulatory Affairs, Data Management, Medical Writing and Financial Management and I am very pleased to handover the webinar in the safe and talented hands of Dr Prashant Bodhe who will moderate the webinar.

Over to you Dr. Bodhe

Aptar Pharma

Container Closure Systems Testing: Leak Detection and Extractable/Leachable Studies in an Age of Complex Drug Formulations

26May2022

Next Breath: a leader in analytical testing

NextBreath
an Aptar pharma company

Next Breath is an intellectual leader in the field of **inhalation, nasal spray, eye care, dermal and injectable drug product testing and regulatory strategy.**

Expertise

- Extraction Studies
- Migration Studies
- Leachables Programs
- Stability Studies
- Regulatory ready documentation

How Next Breath Services can help you

- Support Services for Injectable Delivery Systems that include compatibility **stability, Extractables & Leachables,** and toxicological assessment.
- **Global Regulatory support** for navigating quality expectations for component qualification, validation and regulatory compliance **(INDs, NDAs & ANDAs).**
- Proven **track record** of working with regulatory agencies to ensure a higher product approval rate.
- Strong regulatory relations with the **United States, Europe, Canada, Brazil, India and the Americas.**
- **cGMP compliant laboratory,** FDA inspected, ISO 17025 Accredited and EQFAR certified laboratory through ANVISA.
- **DEA License** for controlled drug substances (schedule II-V)

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Extractables and Leachables

Extractable

Compounds in the component released by harsh chemicals

Extractable: Potential Compound Migration

- A chemical species extracted from a container or closure material under exaggerated conditions

Leachable

Compounds in the drug product in real life storage conditions

Leachable: Actual Compound Migration

- Chemical species found in the drug product or placebo under normal conditions
- Represent real life conditions of use for the drug product

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Why do we care about Extractables and Leachables?

Important to evaluate the potential impact of primary packaging on the long-term quality of drug products

Essential for demonstrating long-term stability of drug products

Potential for migration of toxic impurities into the drug product matrix

Manufacturing Componentry | **Primary Container Closure System** | **Secondary Packaging**

Potential Leachable Sources

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

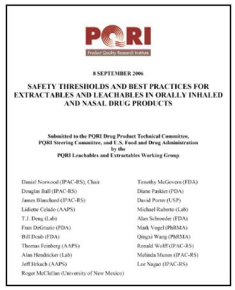
Regulatory Aspects

E&L Guidelines

- Under development by Industry and Regulatory Working Groups

Product Quality Research Institute (PQRI)

- Draft Guideline for Parenteral and Ophthalmic
- Drug Products (POPD published)
- FDA currently reviewing thresholds
- **SCT for injectables = 1.5 µg/day**



PQRI

6 SEPTEMBER 2006

SAFETY THRESHOLDS AND BEST PRACTICES FOR EXTRACTABLES AND LEACHABLES IN ORALLY INHALED AND NASAL DRUG PRODUCTS

Submitted to the PQRI Drug Product Technical Committee, PQRI Steering Committee, and U.S. Food and Drug Administration by the PQRI Leachables and Extractables Working Group

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Relevant USP Chapters

- **<661> / <661.1> - Plastic Packaging Systems / Plastic Materials of Construction**
  - Describes materials of construction and corresponding test methods
- **<661.2> - Plastic Packaging Systems for Pharmaceutical Use**
  - Provides generalized guidance for: biological reactivity, physicochemical tests, and chemical safety assessments in the scope of plastic packaging systems for the use of containing pharmaceutical materials
- **<1663> - Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
- **<1664> - Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Deliver Systems**

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Guidelines and Pharmacoepia Chapters

7

- Guidelines to consider
  - PQRI
  - ICH Q3A/B, M7
  - FDA
  - USP

GatewayAnalytical

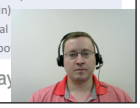
Assessing Risk

Degree of Concern Associated with the Route of Administration	Likelihood of Packaging Component – Dosage Form Interaction		
	High	Medium	Low
Highest	• Inhalation aerosols and sprays	• Injections and injectable suspensions • Inhalation solutions	• Sterile powders and powders for injection • Inhalation powders
High	• Transdermal ointments and patches	• Ophthalmic solution and suspensions • Nasal aerosols and sprays	
Low	• Topical solutions and suspensions • Topical and lingual aerosols • Oral solutions and suspensions		• Oral tablets and oral capsules (hard and soft gelatin) • Topical • Oral po

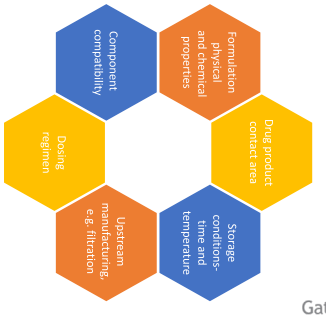
Modified from PQRI POPD Working Group Update, 2020

Delivering solutions, shaping the future.

GatewayAnalytical



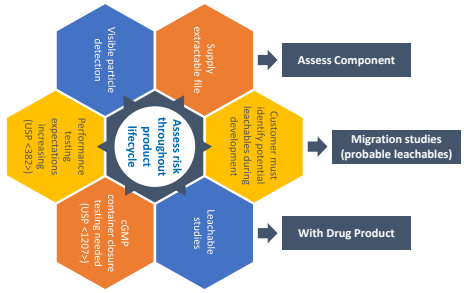
Drug Product Risk Assessment Factors



Delivering solutions, shaping the future.

GatewayAnalytical

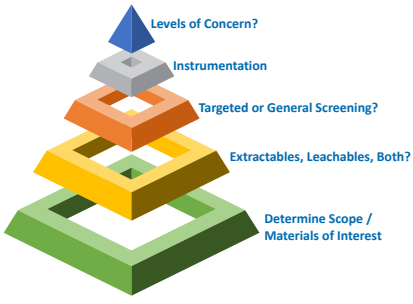
Risk Assessment



Delivering solutions, shaping the future.

GatewayAnalytical

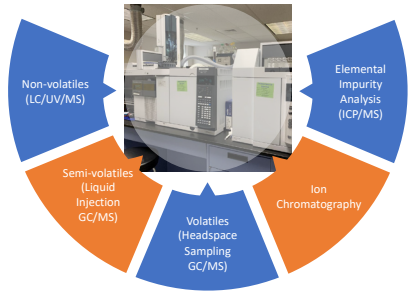
Study Design



Delivering solutions, shaping the future.

GatewayAnalytical

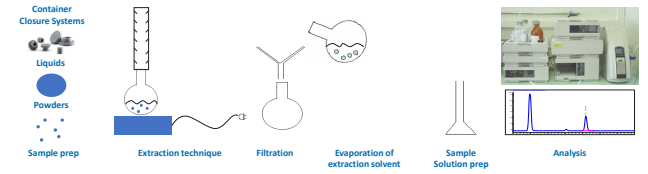
Instrumentation



Delivering solutions, shaping the future.

GatewayAnalytical

Execution Workflow



Materials

Microwave oven
Reflux
Soxhlet
Sonication
Accelerated Solvent Extractor

Solvents of different polarities:
Dichloromethane
Water
Isopropanol
Hexane
Etc.

LC-UV-MS
GC-MS
IC
ICPMS

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

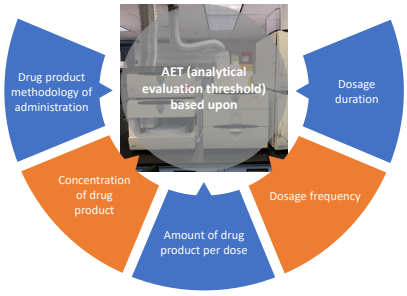
Targeted or General Screening Approach?

	General Screening	Targeted Screening
		
Advantages	• Unbiased • Large MW coverage range	• Very sensitive • More accurate quantitation
Disadvantages	• Lower sensitivity • Semi-quantitative	• Requires authentic standard material • May miss out on analytes outside of the targeted method

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

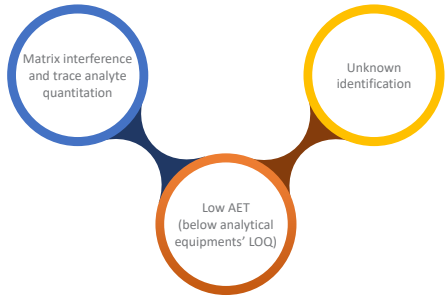
Levels of Concern



Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Common E&L Issues

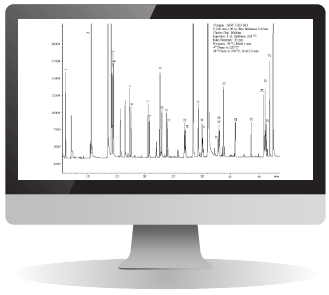


Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Matrix interference and trace analyte quantitation

- How can we mitigate the impact of additional peaks from interfering with our analysis?
  - Use of control samples
  - Examination of peak purity
  - Clean up the sample matrix
- How can we perform quantitation at trace levels?
  - Targeted >> sensitivity than a general scanning approach
  - Generate a method very specific to the target analyte's precursor and fragment



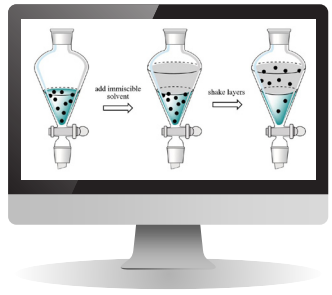
Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Unique Techniques to Accommodate Low AETs

Sample concentration techniques

- Non-volatiles:
  - Evaporation
- Semi-volatiles:
  - Liquid/liquid extraction
  - Dispersive liquid/liquid microextraction (DLLME)
- Volatiles
  - Hanging droplet microextraction/ solid phase micro extraction (SPME)



Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Unknown Identification Techniques

- MS Libraries
  - Commercial libraries are available, particularly for GC/MS software (NIST, Wiley, etc.)
- Molecular formula generation using empirical accurate mass / isotope spacing on a high resolution instrument
- MS/MS fragmentation and RT match with that of an authentic standard material needed for absolute confirmation

Delivering solutions, shaping the future.

GatewayAnalytical
an Aptar pharma company

Summary

20

- Leachable programs
  - Regulatory expectation
  - Risk assessment
- PQRI, USP and other guidelines provide context, but not a "how to"
- Planning for a program requires determining the project scope and a dialogue with your laboratory
- Common pitfalls can be overcome
- Next Breath's goal is to accelerate and derisk your drug development journey

GatewayAnalytical
an Aptar pharma company

Agenda

21

1. Overview of USP <1207> for container closure integrity testing.
2. Learn why the FDA now prefers deterministic leak detection methods over traditional probabilistic methods.
3. Regulatory Considerations
4. Review common applications of leak detection for sterile containers.
5. Discuss the Gateway Analytical approach to CCIT studies.

GatewayAnalytical
an Aptar pharma company

Overview of USP <1207>

<1207> Package Integrity Evaluation – Sterile Products

GatewayAnalytical
an Aptar pharma company

<1207> Package Integrity Evaluation – Sterile Products

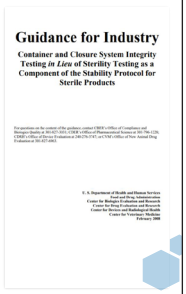
23

Provides guidance on the integrity assurance of nonporous packages intended for sterile pharmaceutical products.

Provides instruction on topics of:

- Leaks
- Leakage rate
- Package sealing/closure mechanisms

Explains how packages that conform to specified leak limits help ensure a contained product meets and maintains sterility and physiochemical specifications.



Guidance for Industry

Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products

GatewayAnalytical
an Aptar pharma company

<1207> Package Integrity Evaluation – Sterile Products

24

States: "*The integration of package integrity assurance as a key component of the entire product life cycle is stressed.*"

Guidance provided for:

- Selection of leak testing methodologies.
- Validation of leak testing methodologies.
- Use of leak testing methodologies.
- Package seal quality testing.

Detailed recommendations are provided in three subchapters:

- *Package Integrity Testing in the Product Life Cycle—Test Method Selection and Validation* <1207.1>
- *Package Integrity Leak Test Technologies* <1207.2>
- *Package Seal Quality Test Technologies* <1207.3>

GatewayAnalytical
an Aptar pharma company

The 'Product-Package' and 'Container-Closure System' Relationship in Package Integrity Assurance

Product-Package: refers to the container-closure system plus the product contents. *Example: finished products such as vials and prefilled syringes.*

Container-Closure System: consists of the primary and secondary packaging components that ensure correct package assembly. *Example: Glass vial + rubber stopper + aluminum cap = sealed stoppered vial package.*

Suitable **container-closure systems** store and protect pharmaceutical product.

"Thus, sterile **product-package integrity** is the ability of a sterile product container-closure system to keep product contents in, while keeping detrimental environmental contaminants out."

GatewayAnalytical

Product Quality Risks Posed by Leaks of Concern

Table 1. Product Quality Risks Posed by Leaks of Concern

Leaks of Concern	Product Quality Risks Posed by Leaks
Capable of allowing entry of microorganisms	Failure of product sterility quality attribute
Capable of allowing escape of the product dosage form or allowing entry of external liquid or solid matter.	Failure of relevant product physiochemical quality attributes
Capable of allowing change in gas headspace content. For example, loss of headspace inert gases (e.g., nitrogen), loss of headspace vacuum, and/or entry of gases (e.g., oxygen, water vapor, air).	Failure of relevant product physiochemical quality attributes and/or hindrance of product access by the end-user.

GatewayAnalytical

Notes on Integrity Test Methods

Integrity test methods vary in:
- Application
- Detection limit
- Detection range
- Precision
- Specificity

No one test method is appropriate for all packages

No one test method is appropriate for all leak testing applications.

USP <1207> guides user in the selection process for package integrity test methods.

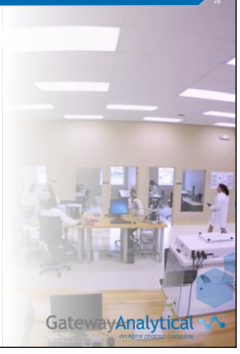
GatewayAnalytical

Development & Validation of Leak Tests

Leak tests require optimization and validation for each product-package application.

Method development and validation are essential for optimizing test method application.

Science- and risk-based approaches may allow for broader application of test methods based on circumstances.



GatewayAnalytical

Regulatory Preference for Deterministic CCIT Methods

GatewayAnalytical

<1207.1> Regulatory Expectations of Method Development and Validation

<1207.1> discusses package integrity testing in the product life cycle.

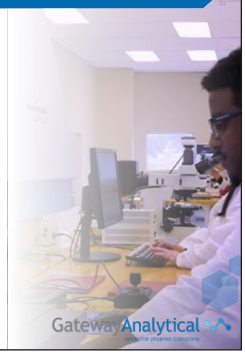
Three product life cycle phases are discussed:
1. Package development, and package processing and assembly validation.
2. Product manufacturing.
3. Commercial product shelf-life stability assessments.

Further reading provides information on how to select, develop, and validate leak test methods.

GatewayAnalytical

<1207.1> Test Method Selection Criteria

- No single package leak test or package seal quality test method is applicable to all product–package systems.
- Test method selection is made on a product–package on a case-by-case basis.
- Package test method selection is as a function of product life-cycle phase, along with important integrity considerations.
- <1207.2> provides information guiding the selection and proper use of leak test technologies (also called methodologies, approaches, or methods).

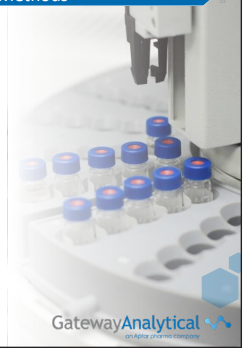


<1207.1> Section 3.5: Deterministic or Probabilistic Methods

- A "probabilistic leak test method" relies on a series of sequential and/or simultaneous events each associated with uncertainties, yielding random outcomes described by probability distributions.
- The findings are associated with uncertainties that necessitate larger sample sizes and rigorous test condition controls to obtain meaningful results.
- Typically, sample size and test condition rigor are inversely related to leak size.
- Therefore, probabilistic leak test methods are more challenging to design, develop, validate, and implement, especially when used to find leaks near the upper and lower limits of the test method's detection range.

<1207.1> Section 3.5: Deterministic or Probabilistic Methods

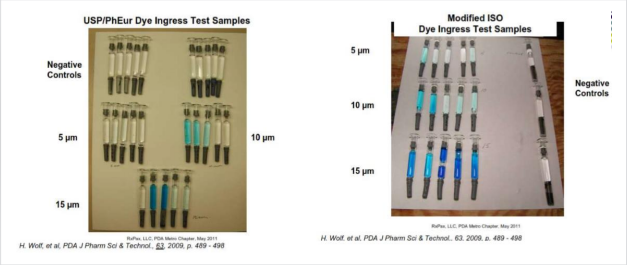
- A "deterministic leak test method" is one in which the leakage event is based on phenomena that follow a predictable chain of events, and leakage is measured using physicochemical technologies that are readily controlled and monitored, yielding objective quantitative data.
- Most deterministic leak test methods rely on the predictable movement of gas that inevitably occurs through an open leak path, given specific differential pressure and/or partial pressure test.
- Deterministic methods are characterized as being capable of reproducibly detecting leaks at clearly defined and predictable detection limits.
- Because most deterministic leak test methods described in <1207> require no special test sample preparation, sample preparation error is eliminated.



<1207.1> Section 3.5: Regulatory Preference for Deterministic Methods

- A deterministic leak test method having the ability to detect leaks at the product's maximum allowable leakage limit **is preferred** when establishing the inherent integrity of a container–closure system.
- Deterministic methods may also be chosen if test sample quantities are **limited**, when checking for **rarely occurring leaks of concern** and/or when the potential risk for **failing to find leaks** of a given size or type is too great.

Example: Probabilistic Method – Dye Ingress



Example: Deterministic Method – Laser-based Gas Headspace Analysis

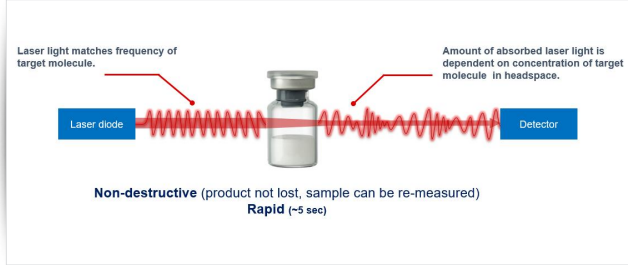


Image Source: Lighthouse Instruments

Top Five Applications for Laser-Based Gas Headspace Analysis

1. **CO_2 overpressure vessel and CO_2 analyzer.**
Excels for inherent CCI testing on empty and product-filled product-package systems. This technique excels because it **does not** require a modified atmosphere headspace. Like Dye Ingress testing, but with the advantages of **deterministic modern technology.**

2. **Lyophilized products stored under vacuum.**
Test measures the headspace O_2 concentration.
Laser-Based Gas Headspace Analysis is the **industry standard** for this type of test.

GatewayAnalytical
an Aptar pharma company

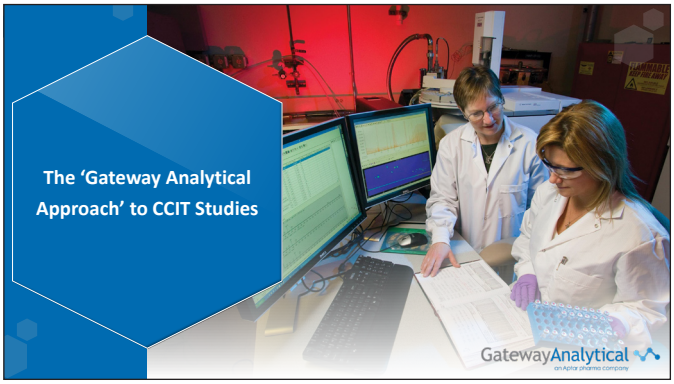
Top Five Applications for Laser-Based Gas Headspace Analysis

3. **Products stored/shipped on dry ice.** (Same conditions as Item #4 below)

4. **Products stored on the vapor phase above liquid nitrogen.**
Problem: CCI breaches in the vial/stopper interface can occur during Deep Cold Storage but reseal themselves once removed from storage.
Advantage: Laser Headspace analysis **can still detect** the presence of these breaches in CCI after the defect has resealed itself.

5. **Products purged with an inert gas at 1 atm total pressure.**
Test measures the headspace O_2 concentration.
No sample or pre-conditioning steps required.
Sensitivity in the test method can detect **partial pressure** changes.

GatewayAnalytical
an Aptar pharma company



Frequency Modulation Spectroscopy (FMS) Laser Headspace Analysis at Gateway Analytical

Frequency Modulation Spectroscopy (FMS) Laser Headspace:
Measure partial pressure (Torr or %atm) of gas concentrations in the headspace of a product-package system.

Image Source: Lighthouse Instruments

GatewayAnalytical
an Aptar pharma company

Frequency Modulation Spectroscopy (FMS) – Carbon Dioxide Analyzer

- Most used for liquid products (frozen or liquid) in vials.
- Can support studies on products and vials that are stored at room temperature, refrigerated, -20°C/-80°C
- Support -80°C studies for the testing of frozen product shipped on dry ice for transport. Dry ice sublimation for CO2 exposure
- Support -20°C studies for the testing of frozen product. CO2 gas pumped into freezer for exposure
- Support refrigerated studies for the testing of chilled product and ambient studies. CO2 overpressure vessel used for exposure

Image Source: Lighthouse Instruments

GatewayAnalytical
an Aptar pharma company

Frequency Modulation Spectroscopy (FMS) – Oxygen Analyzer

- Lyophilized products or products with a vacuum headspace or inert gas headspace (nitrogen)
- Internal pressure concentration monitoring of oxygen levels during the filling of oxygen-sensitive products.
- Can support in the process of optimization and validation of purging systems on filling lines.

Both Systems Can Support:

- Stability studies, end-of-shelf life studies.
- Packaging permeation studies with the ability to take measurements over a defined period of time

Image Source: Lighthouse Instruments

GatewayAnalytical
an Aptar pharma company

Every Vial Configuration Should be Validated

Vial/Stopper/Seal components are validated as a whole configuration.

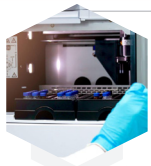
Changing one of these components in a vial configuration is enough of a change to require an additional validation with the new component.

Multiple vial configurations can be validated if you suspect that you are changing suppliers or types of components.

May want to perform CCI studies (prior to validation) to evaluate CCI with different vial configuration combinations and storage conditions prior to determining your final vial configuration and storage.

GatewayAnalytical

Gateway Analytical's USP<1207> Program



1

Program Setup/Proof of Concept

Acquire all raw materials and information needed for the study. This includes vials, stoppers and caps, technical drawings, and other vial configuration info

Creation of change parts and flame sealed standards

Test and evaluate the repeatability, precision, and accuracy of the flame sealed standards within the instrument.

2

Method Development

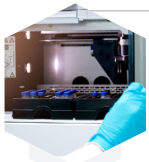
Leak test parameters and time testing windows are developed and optimized.

This is done through the creation of different controls with known defect sizes

Testing occurs over multiple days with multiple times in and out of storage

GatewayAnalytical

Gateway Analytical's USP<1207> Program



3

Method Validation – the following are properties of a validated test method:

Accuracy
Precision
Specificity
Detection Limit
Quantitation Limit
Linearity
Range
Robustness

GatewayAnalytical

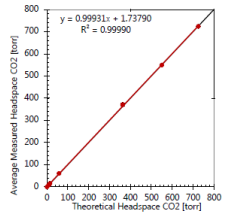
Instrument and Equipment Qualification ("Program Set-up")

Unique Flame sealed standards are created for the product-package system.

Linearity developed according to USP<1207> using known gas concentrations.

Allows the instrument to be calibrated prior to sample measurement based on product-package configuration properties.

Keep in mind, vials of different compositions have different properties that can affect the CCI analysis of the vials (example: glass, CZ, etc.).



GatewayAnalytical

Method Development

Measurements are collected for the following samples:

- Product-filled samples.
- Negative controls.
- Laser-drilled defect positive controls
- Gross Positive Controls

Product-filled samples are tested to determine if an inherent level of tracer gas is present.

- Allows for the creation of "Accept/Reject" criteria for method validation.

Positive controls demonstrate the leak test system can detect the molecule of interest in the product-package configuration.

- Laser drilled defects (~5µm) establish the lower limit of detection.
- Gross positive controls (~838 µm) establish the upper limit of detection.

GatewayAnalytical

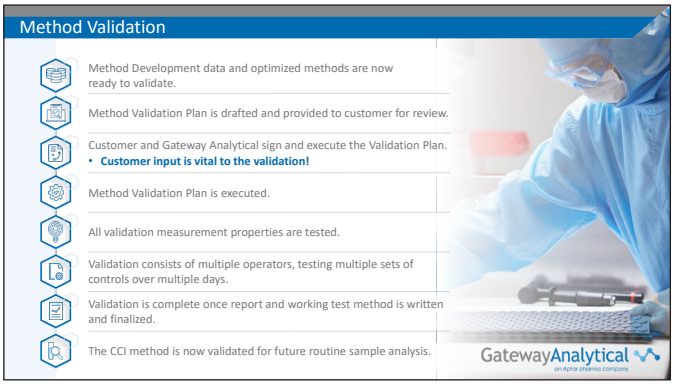
Method Development

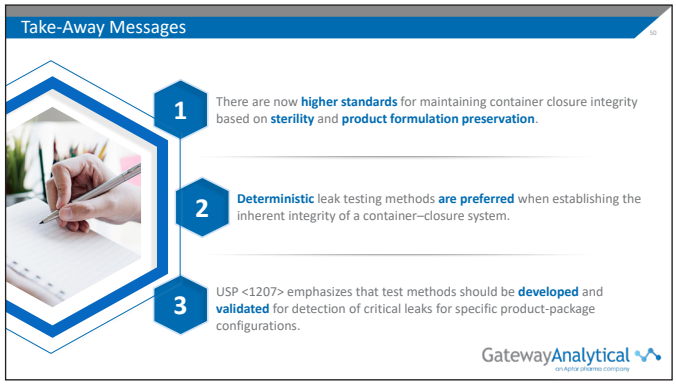
Negative Controls

- Demonstrate the crimping process is not the cause of the detected molecule in the positive controls.

Method development data is then used to create the validation plan and set the accept/reject limits.

GatewayAnalytical





Vote of Thanks by Ms Sapna Patil, Deputy Secretary - General, IDMA

It gives me great pleasure to bestow the vote of thanks for this exciting, interesting and informative webinar on "Container closure systems testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations''. We had over 300+ registrations for this webinar which proves how important this subject is to the pharma industry. I, therefore, specially thank Aptar Pharma for partnering with IDMA and giving us such innovative & educative webinars throughout the year.

In today's webinar, we understood Why do we care about Extractables and Leachables? Their relevant USP chapters and Guidelines. There was a nice presentation of the instrumentation and techniques forLeak detection and Extractable/ Leachable studies.

The Next Breath's goal is to accelerate and derisk your drug development journey.

We deliberated on the Overview of USP <1207> Package Integrity Leak Test Technologies – Sterile products. Learned why the FDA prefers deterministic leak detection methods over traditional probabilistic methods. The Regulatory expectations of method development and validation. The takeaway points emphasized that test methods should be developed and validated for detection of critical leaks for specific product.

On behalf of our National President, Dr. Viranchi Shah and our Secretary General, Mr. Daara Patel, we immensely thank Mr. Scott and Mr. Patrick Dayton for educating us and enlightening us on this interesting topic of Container closure systems testing and Extractable/ Leachable studies. We, at IDMA, would like to put on record our sincere thanks & gratitude to Mr. Kanwal Tikoo of Aptar Pharma for continuously supporting us and giving our members such innovative webinars.

We sincerely thank Mr. S R Vaidya our Chairman of the MSME Committee for always supporting us and specially for all the Webinars with Aptar Pharma. Vaidya Sir many thanks for all your support, co-operation & co-ordination. It is our pleasure working with you always.

We thank Dr. Prashant Bodhe, Principal Consultant at CliniSearch for his valuable time and for his excellent moderation of this webinar. There was wonderful question and answer session.

We take this opportunity to thank all the participants for their time and for their active participation which enabled this webinar to be more lively and vibrant.

And last but not the least, we thank Ms. Prachi and her team including Mr. Vignesh at Aptar Pharma and special thanks to my team at IDMA for their diligent support and co-ordination in making this webinar a grand success.

Now I request Vaidya sir to say a few words and close this webinar.

Thank you everyone and enjoy your evening.

● ● ●

medGrids®
FROM CARING TO SHARING

HEALTHCOPEIA

PRESENTS

HEALTHCOPEIA SOUTH ASIA SUMMIT - 2022

PHARMACEUTICAL SERIALIZATION IN INDIA : SCOPE AND CHALLENGES

SATURDAY
23RD JULY 2022

VIVANTA
PANJIM - GOA

PANEL DISCUSSION:
MATCHING INDUSTRY EXPECTATIONS WITH PHARMACY TRAINING IN INDIA

Healthcopeia Foundation is an organization that strives to health educate people from all walks of life. It aims to bring forth subjects of public interest in the limelight, such that the nation's wheel of progress always move ahead. From providing contemporary treatments at an affordable cost to conducting Conferences and Seminars of National and International Importance, Healthcopeia has always emerged as an Impeccable Leader.

With its previous event, HEALTHCOPEIA CONGRESS – 2022 held on 7th May 2022 at FICCI Federation House, New Delhi, Healthcopeia endeavored to impart ground-level knowledge about
ANTI-COUNTERFEITING, ANTI-PIRACY AND BRAND PROTECTION.

Now Healthcopeia Foundation is determined to broaden its horizon with HEALTHCOPEIA SOUTH ASIA SUMMIT – 2022 Where Industry and Academia leaders will share their thoughts on GOI ongoing initiatives to increase quality of medicines in the country by introduction of Serialization.

SUPPORTED BY	EVENT PARTNER
IDMA	NCPM

OUR SUPPORTERS AND PARTNERS IN PREVIOUS EVENTS

Indian Pharmacopoeia Commission (IPC)
Ministry of Health & Family Welfare
Govt. of India

200 usp The standard of trust

FICCI

IDMA

NCPM

SAHARA NEWS NETWORK

British Ayurvedic Medical Council

WORLD BOOK OF RECORDS

GHADI DETERGENT

KAMKUS Pioneer in Integrated Medicine

EXTRAORDINARY AND PLENIPOTENTIARY DIPLOMATIST

VIROKILL

ICH

CHANAKYA

Call for Papers: 8th National Conference on Economics of Competition Law, 2023 - reg.

Call for Papers

The Competition Commission of India (CCI) will organize the 8th National Conference on Economics of Competition Law on **3rd March, 2023** in New Delhi.

Objectives

This conference aims to:

- Stimulate research and debate on contemporary issues in the field of economics of competition law
- Develop a better understanding of competition issues relevant to the Indian context
- Draw inferences for implementation of competition law in India

For details please scan QR code

Who should participate?

The conference targets economists including scholars, practitioners and competition agency officials with a keen interest in economics of competition law and policy. Co-authored papers are allowed. However, one of the authors should be an Indian citizen having expertise/ specialization in Economics.

Submission of papers

A 1000-word abstract of the paper including research questions, methodology and expected results along with one-page curriculum vitae and contact details should be submitted initially.

Authors of selected abstracts will then be invited to submit full original papers of not more than 6000 words.

Themes

The Conference is expected to cover a wide range of related themes. However, papers in following themes are encouraged:

1. Market definition, measuring market power and abuse of dominance

Issues like empirical methods of defining markets, measuring market power, and assessment of exclusionary unilateral conduct etc. may be covered among others.

2. Vertical restraints and competition

Vertical restraints can have many procompetitive as well as anticompetitive effects. Papers may explore areas such as resale price maintenance, assignment of exclusive territories or exclusive dealing, tying and bundling and circumstances under which these restrictions have anti-competitive effects.

3. Horizontal agreements and cartelization

Prohibition of collusive conduct of firms is a key component of competition law. Papers may explore issues such as economics of collusion, information exchange, price signaling, facilitating factors for cartels, detecting and discouraging cartels etc.

4. Economics of platform markets and challenges for antitrust enforcement

New digital products and business models as well as the special characteristics of digital markets have created new challenges for enforcement and competition policy. Papers may explore new tools and techniques that the discipline of economics offers for assessing competition issues in platform markets.

5. Intellectual Property Rights and competition law

Competition law will be concerned not with the legitimate exercise of an IP right, but with efforts of the holders of this right to expand the scope, either to new products, or beyond a certain time or by conditioning access to the right on restrictions. Papers may explore areas of recent concerns in the IP-competition law interface.

6. Price and non-price effects of mergers

Economic analysis is playing an increasingly important role in merger review. Papers may focus on recent developments in estimating the effects of mergers (merger simulation, diversion ratios, pricing pressure indices, etc.), innovation effects and welfare effects of mergers including vertical or conglomerate mergers, issues in the use of appropriate remedies, that is, adoption of structural and/or behavioral remedies.

7. Any other issues related to competition policy and law

There is no conference fee.

Post-conference publication

Depending on the quality of submissions, some papers may be considered for publication by the CCI.

Financial support

Paper presenters at the Conference shall be provided financial support.

Venue

New Delhi, India

Important dates and deadlines

1.	***Last date of submission of abstracts***	***1st August, 2022***
2.	***Review, Selection and intimation to authors***	***1st October 2022***
3.	***Last date for submission of full papers***	***1st December 2022***
4.	***Review and Finalization of papers***	***1st February 2022***
5.	***Conference/ webinar date***	***3rd March 2023***

Selection of themes and speakers

The CCI will have complete discretion in deciding the themes of the sessions based on the papers received as well as in selecting the speakers.

Papers based on empirical research that can inform competition enforcement and policy are encouraged.

Contact us

Abstract along with CV may be sent to ***ecoseminar@cci.gov.in*** . The CV should necessarily include education, work experience and publication in the area of economics, if any. Requests for further information or any other queries may also be sent to this email address.

● ● ●

THE ECONOMIC TIMES

Smart Pharma

Summit 2022

28 JUNE 2022

Sahara Star Mumbai

Above and beyond innovations: The Future of Pharma

ETSMARTPHARMA

REGISTER NOW

Pharmaceutical businesses may use cutting-edge technologies like augmented reality (AR), artificial intelligence (AI), Blockchain, and additive manufacturing to speed up the research and development process, produce individualised medicines, and perform testing in novel ways. With this preview in mind, **The Economic Times Smart Pharma Summit 2022** brings to you this meticulously curated conference for Pharma leaders revolving around the technology trends, government policies, automation, supply chain management strategies, and strategic leadership.

We have an impressive line-up of speakers excited to inspire and share their industrial knowledge & experience with you!

SPEAKERS

ANJANI KUMAR
CIO, strides pharma

ASHISH PANDEY
CIO, GlaxoSmithKline (GSK)

DHAVAL PANDYA
CIO, Piramal

MANOJ SAXENA
MD, Bayer Zydus Pharma

PRASAD DESHPANDE
Senior VP & Global Head, Supply Chain Management and Central Engineering ,Biocon

SANJEEV NAVANGUL
Managing Director and CEO
Bharat Serums & Vaccines

SAURABH GUPTA
Global head Supply Chain
Lupin

SRIDHAR S
MD, Pfizer

VANI MANJA
Managing Director
Boehringer Ingelheim

You wouldn't want to miss out on the outstanding sessions led by them!

JOIN TODAY!

Supporting Association

Brought to you by ET Edge

Relaxation in provision of submission of 'Bill of Export' as an evidence of export obligation discharge for supplies made to SEZ units in case of Advance Authorisation

Policy Circular No. 39/2015-20, dated 7th June 2022

To
All Regional Authorities of DGFT,
All Exporters/Members of Trade,
All Custom Authorities.

1. One of the documentary requirements prescribed under 'Guidelines for Applicants' of ANF-4F (Application for Redemption) in case of supplies made to SEZ units under Advance Authorisation, states as follows:

"…EP copy of the shipping bill(s) containing details of shipment effected or bill of export in case of export to SEZ…"

2. The above stated requirement of submitting 'Bill of Export' for supplies made to SEZ is prescribed under the Foreign Trade Policy. This requirement was challenged by several exporters before various High courts in the country on the ground of hardships suffered by them due to non-availability of this provision for the period covered upto FTP 2009-14. In most of the cases, Hon'ble Courts have granted relief to the Advance Authorisation holders.

3. Accordingly the issue has been examined and in terms of Para 2.58 of the FTP 2015-2020 (extended upto 30.9.2022), it has been decided to relax this condition of requirement of submission of 'Bill of Export' in case of exports made to SEZ units under Advance Authorisation, for all such supplies made prior to 01.04.2015.

4. Accordingly, for the purpose of discharge of export obligation under Advance Authorisations, in case of supplies made to SEZ units prior to 01.04.2015, the exporters can submit corroborative evidence in lieu of 'Bill of Exports' such as:

a) ARE- 1 form duly attested by jurisdictional Central Excise/GST Authorities of AA holder.

b) Evidence of receipt of the supplies by the recipient in the SEZ

c) Evidence of payment made by the SEZ unit to the AA holder

5. This Policy Circular is issued with the approval of DGFT.

File no.1/94/180/025/AM20/PC-4

Vijay Kumar, Addl. Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

Amendments in Para 2 (b)(i) of the Guidelines for applicants under ANF-4F of Handbook of Procedures 2015-2020

Public Notice No.11/2015-2020, dated 07 June, 2022

In exercise of powers conferred under Paragraph 1.03 and 2.04 of the Foreign Trade Policy 2015-2020, as amended from time to time, the Director General of Foreign Trade hereby makes the following amendments in Para 2 (b)(i) of the Guidelines For Applicants under ANF-4F of Handbook of Procedures 2015-2020:

2(b) For Deemed Exports

(i) A copy of the invoice or a statement of invoices duly signed by the unit receiving the material certifying the item of supply, its quantity, value and date of such supply. However in case of supply of items which are non

excisable or supply of excisable items to a unit producing non excisable product(s), a project authority certificate (PAC) certifying quantity, value and date of supply would be acceptable in lieu of excise/GST certification. However, in respect of supplies to EOU/EHTP/ STP/BTP, a copy of CT-3/ARE-3 duly signed by the jurisdictional excise/GST authorities certifying the item of supply, its quantity, value and date of such supply can be furnished in lieu of the excise/GST attested invoice (s) or statement of invoices as given above. However in case of supply of the product by the Intermediate supplier to the port directly for export by the ultimate exporter (holder of Advance Authorisation or DFIA) in terms of paragraph 4.30 of HBP, copy of the shipping bill with the name of domestic supplier as Intermediate supplier endorsed on it along with the file No./ Authorisation No. of the ultimate exporter and the intermediate supplier shall be required to be furnished.

Effect of this Public Notice: Para 2 (b)(i) of the 'Guidelines For Applicants' under ANF-4F of Handbook of Procedures 2015-2020 has been amended to simplify the procedure and reduce the compliance burden for applying EODC in case of deemed exports.

File No.01/94/180/234/AM20/PC-4

Santosh Kumar Sarangi, Director General of Foreign Trade, Ex-officio Additional Secretary, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, Udyog Bhawan, New Delhi

● ● ●

CUSTOMS MATTERS

Anti-Dumping Duty (ADD) on import of Toluene Di-isocyanate (TDI) originating in or exported from China PR, Japan and Korea RP - reg.

Notification No. G.S.R.417(E), 19/2022-Customs (ADD), dated 3rd June, 2022

Whereas, the designated authority *vide* initiation notification No. 7/26/2021-DGTR dated 27th August, 2021, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 27th August, 2021, has initiated review in terms of sub-section (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act) read with rule 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995 (hereinafter referred to as the said rules), in the matter of continuation of anti-dumping duty on imports of **"Toluene Di-Isocyanate (TDI)"** (hereinafter referred to as the subject goods) falling under Tariff Item 2929 10 20 of the First Schedule to the Customs Tariff Act, originating in or exported from **China PR, Japan and Korea RP** (hereinafter referred to as the subject countries), imposed vide notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.3/2018-Customs(ADD), dated 23rd January, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.61(E), dated the 23rd January, 2018, and has requested for extension of the said anti-dumping duty in terms of sub-section (5) of section 9A of the Customs Tariff Act.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the said rules, the Central Government hereby makes the following further amendment in the notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.3/2018-Customs(ADD), dated the 23rd January, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 61(E), dated the 23rd January, 2018, namely:-

In the said notification, after paragraph 2 and before the Explanation, the following paragraph shall be inserted, namely-

"3. Notwithstanding anything contained in paragraph 2, the anti-dumping duty shall remain in force up to and inclusive of the 27th September, 2022, unless revoked, superseded or amended earlier".

F.No.CBIC-190354/121/2022-TRU

Nitish Karnatak, Under Secretary, Ministry of Finance, Department of Revenue, New Delhi

Note: *The principal notification No.03/2018-Customs (ADD), dated the 23rd January, 2018, was published in the Gazette of India, vide number G.S.R.61(E), dated the 23rd January, 2018, and was last amended by notification No.2/2021-Customs (ADD), dated the 28th January, 2021, published in the Gazette of India, vide number G.S.R.53(E), dated the 28th January, 2021.*

● ● ●

Anti-Dumping Duty (ADD) on imports of "Styrene Butadiene Rubber" originating in or exported from European Union, Korea RP and Thailand - reg.

Notification No.17/2022-Customs (ADD), dated 30th May, 2022

Whereas, the designated authority vide initiation notification No.7/31/2021-DGTR dated 10th February, 2022, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 10th February, 2022, has initiated review in terms of sub-section (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act) read with rule 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995 (hereinafter referred to as the said rules), in the matter of continuation of anti-dumping duty on imports of **"Styrene Butadiene Rubber (SBR) of 1500 series and 1700 series"** (hereinafter referred to as the subject goods) falling under sub-heading 4002 19 of the First Schedule to the Customs Tariff Act originating in or exported from **European Union, Korea RP or Thailand** (hereinafter referred to as the subject countries), imposed vide notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.43/2017-Customs(ADD), dated 30th August, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (i), vide number G.S.R.1123(E), dated the 30th August, 2017, and has requested for extension of the said anti dumping duty in terms of sub-section (5) of section 9A of the Customs Tariff Act.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the said rules, the Central Government hereby makes the following amendment in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.43/2017-Customs(ADD), dated the 30th August, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.1123(E), dated the 30th August, 2017, namely:-

In the said notification, after paragraph 2, the following paragraph shall be inserted, namely-

"3. Notwithstanding anything contained in paragraph 2, the anti-dumping duty imposed under this notification shall remain in force up to and inclusive of the 31st October, 2022, unless revoked, superseded or amended earlier.".

F.No.CBIC-190354/133/2022-TO(TRU-I)-CBEC

Rajeev Ranjan, Under Secretary, Ministry of Finance, Department of Revenue, New Delhi

Note: *The principal notification No.43/2017-Customs, dated the 30th day of August, 2017 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.1123(E)., dated the 30th day of August, 2017.*

● ● ●

In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Medical Device Parks

Rajya Sabha Unstarred Question No. 3712

Shri Iranna Kadadi:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the number of Medical Device Parks that have been opened till now particularly in Karnataka;

(b) the rationale employed to select States under this scheme;

(c) the steps being taken to promote research and invention at these parks; and

(d) the details of an invention or innovation, if any, that has taken place in these parks in Karnataka till now?

Answered on 5th April, 2022

A. (a) to (d): The Department is implementing the scheme "Promotion of Medical Devices Parks", with a total financial outlay of Rs. 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to Rs. 100 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025 and the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

The criteria for selection of Medical Device parks under the scheme has been mentioned in the guidelines of the scheme and the same may be seen at **https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20the%20Scheme%20Promotion%20of%20Medical%20Devices%20Parks_1.pdf.**

Under the scheme, Department of Pharmaceuticals has received proposals from 16 States/Union Territories including Karnataka. The proposals were evaluated as per the criteria given in the scheme guidelines and final approval for financial assistance of Rs. 100 crore each has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh.

The Department is implementing the "Promotion of Medical Devices Parks" scheme, with the objectives

- to create world class infrastructure facilities in order to make Indian medical device industry a global leader,
- to provide easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness, that will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market and
- to exploit the benefits arising due to optimization of resources and economies of scale.

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwanth Khuba)

Support for Patients of Rare Diseases

Rajya Sabha Unstarred Question No. 3765

Shri Mahesh Poddar:

Q. Will the Minister of **HEALTH AND FAMILY WELFA**RE be pleased to state:

(a) the number of lives that have been lost because of rare diseases in the country during the last five years;

(b) the amount of money that has been collected from crowdfunding to support such patients and the details thereof; and

(c) the support extended under Rashtriya Arogya Nidhi during the last three years and the details thereof?

Answered on 5th April, 2022

A. (a) As per data available on the National Registry of Rare and Other Inherited Disorders (NRROID), out of total 5850 patients enrolled from November 2019 onwards, 251 patients have died as on date.

(b) The amount of money that has been collected as on date from crowdfunding to support such patients is Rs. 1,18,016 (Rupees One Lakh Eighteen Thousand Sixteen Only).

(c) The total amount released by the Government for treatment of Rare Disease Patients during the last three years, is as follows:

(i) Year 2019-20 – Rs. 1.30 Crore

(ii) Year 2020-21 – Rs. 10 Crore

(iii) Year 2021-22 – Rs. 03.15 Crore

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

In Lok Sabha

Trade with Russia

Lok Sabha Unstarred Question No. 5580

Shri A. Ganeshamurthi:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether any proposal has been mooted with Russia to work out a mechanism using other currencies like Indian rupee for settlement of trade with that country, in view of payments stuck due to sanctions on Russian banks;

(b) if so, the details thereof;

(c) the total volume of bilateral trade with Russia during the last two years and the current year;

(d) whether India would adopt floating exchange rate instead of fixed exchange rate since it is a fact that ruble has crashed recently; and

(e) if so, the details thereof?

Answered on 6th April, 2022

A. (a) & (b) : The regulatory framework for settlement of trade in INR and other currencies is governed by the Foreign Exchange Management (Deposit) Regulations, 2016, which permit a branch or correspondent outside India to open Vostro account with Authorised Dealer (AD) bank in India. Vide AP DIR Circular No.09 dated 22.11.2019, the scope of Special Non-Resident Rupee (SNRR) Accounts was enhanced by RBI by permitting persons resident outside India (overseas buyers/sellers) to open a non-interest-bearing SNRR account with AD Category-1 banks in India for undertaking bonafide transactions pertaining to trade/trade credits in INR.

(c): Bilateral trade with Russia during the last two years and the current year is given below:

Value in USD million

Years	Russia		
	Exports	Imports	Total Trade
2019-2020	3,017.75	7,093.01	10,110.76
2020-2021	2,655.84	5,485.75	8,141.58
April-February 2022 (P)	3,180.48	8,688.52	11,869.00

(d) & (e) : The exchange rate of the Rupee is largely determined by demand and supply conditions in the foreign exchange market. RBI maintain stability in the foreign market by ensuring orderly conditions without targeting a pre-specified level or band for Rupee's exchange rate.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Requirement and validity of Certified Compliance Report (CCR) issued by the IROs of MoEF&CC/MS of SPCBs/ ROs of CPCB - reg.

F. No. IA3-22/10/2022-IA.III [E 177258], dated 8th June, 2022

To

1. Chairman, Central Pollution Control Board (CPCB).
2. Chairman of all the Expert Appraisal Committees
3. Chairperson/Member Secretaries of all the SEIAAs/SEACs
4. Chairpersons/Member Secretaries of all SPCBs/UTPCCs
5. All the Officers of I.A. Division.

1. The MoEF&CC issued an Office Memorandum (OM) No. J-11011/618/2010-IA.II(1) dated 30/05/2012 which mandates the requirement of Certified Compliance Report (CCR) on the conditions stipulated in the ECs to the existing projects/activities from the concerned Integrated Regional Offices (IROs) of MoEF&CC for consideration of expansion proposals for grant of Environment Clearance under the provisions of EIA Notification, 2006.

2. In order to facilitate the process of obtaining CCR, MoEF&CC issued a circular No. J-11013/ 6/ 2010-IAII(Part) dated 7/09/2017 stating that the concerned Member Secretary(MS) of EAC/SEAC shall make a request to the concerned IRO of MoEF&CC at the time of issuance of ToR for the developmental project. Such request shall be disposed of by the concerned IRO within one month. In case, if the inspection is not carried out within one month, the CCR obtained from concerned Regional Offices of Central Pollution Control Board (CPCB) or MS of respective State Pollution Control Boards shall also be accepted for deliberations by the EAC/SEAC.

3. In all cases involving expansion of any project or activity, CCR is mandatorily required. In this regard, instances have been brought to the notice of this Ministry wherein the Environment Clearance application for expansion projects are being submitted by the project proponent with the CCR older than three years for appraisal by the EAC/ SEAC. Further, project proponents are not submitting CCR for the expansion proposals if the existing unit is running on Consent To Operate (CTO) obtained from the SPCBs/ PCCs.

4. The aforesaid matter has been examined in the Ministry and it has been decided that following procedure shall be adopted by the Member Secretary (MS) of EAC/SEAC while appraising developmental projects which involve expansion, as per the provisions of EIA Notification 2006.

A. Proposals involving expansion of existing EC

i. At the time of issuance of expansion ToR, the MS of EAC/SEAC shall endorse a copy of the ToR to the concerned IRO of MoEF&CC. Based on the same, project proponent shall approach the concerned IRO of MoEF&CC to issue CCR. Such request shall be expeditiously considered and disposed of by the concerned IRO within a time frame of three months from the date of application of project proponent. In case, the CCR is not issued within three months, the project proponent shall approach concerned Regional Offices of Central Pollution Control Board (CPCB) or MS of respective State Pollution Control Boards (SPCB) or State Pollution Control Committees (SPCCs) for the same.

ii. The CCR issued by the concerned Authority shall explicitly state the date of inspection, present status of the implementation of the project along with compliance status to each of the condition prescribed in the EC.

iii. CCR issued by the concerned Authority shall be valid for a period of one year from the date of inspection of the project. The submission of CCR beyond older than one year from the date of inspection shall not be accepted by the concerned MS of EAC/SEAC for placing it before the EAC/ SEAC for carrying out the appraisal process.

iv. Monitoring report issued by concerned IROs in conformity to the above, if available, can also be submitted by the project proponent in place of CCR.

v. Self-certified six monthly Compliance Report for the latest EC shall be sufficient if the project proponent applies for expansion within a period of six months from the grant of previous EC. If such application is submitted beyond the period of six months from the grant of EC, CCR shall be required for the latest EC.

B. Proposals involving expansion of existing project running on the basis of Consent To Operate (CTO) from SPCBs/ SPCCs (without requirement of EC)

i. At the time of issuance of expansion ToR, the Member secretary of EAC/SEAC shall endorse a copy of the ToR to the concerned MS of SPCBs/ SPCCs. Based on the same, project proponent shall request the concerned MS of SPCBs/PCCs to issue CCR on the compliance status to the prescribed CTO conditions. Such request shall be expeditiously considered and disposed of by the concerned SPCBs/SPCCs within a time frame of two months from the date of request of the project proponent. In case, the CCR on CTO conditions is not issued within two months, the project proponent shall approach concerned Regional Offices of CPCB for the same.

ii. The CCR on CTO conditions shall explicitly state the date of inspection, present status of the implementation of the project along with compliance status to each of the condition prescribed in the CTO. Such CCRs shall be forwarded by the concerned Member Secretary of SPCBs/PCCs to the MoEF&CC/SEIAA.

iii. CCR on CTO conditions issued by the concerned SPCBs/PCCs shall be valid for a period of one year from the date of inspection of the project. The submission of CCR older than one year from the date of inspection shall not be accepted by the concerned MS of EAC/SEAC for placing it before the EAC/SEAC for carrying out the appraisal process.

iv. Self-certified Compliance Report for the latest CTO shall be sufficient if the project proponent applies for expansion within a period of one year from the grant/renewal of CTO. If such application is submitted beyond the period of one year from the grant/renewal of CTO, CCR shall be required for the latest CTO.

5. This OM is issued in supersession of OM no. J-11011/618/ 2010-IA.II(I) dated 30/05/2012 & J-11013/6/ 2010-IA.II(Part) dated 7/09/2017 and with the approval of the Competent Authority.

Sundar Ramanathan, Scientist E, Ministry of Environment, Forest and Climate Change, IA Division, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi.

● ● ●

INTERVIEW

Digital roadmap defines the success of technology initiatives

Amit Saluja, Senior Director and Head, NASSCOM CoE, explains the role of technology in pharma manufacturing, while also shedding light on the Smart Manufacturing Forum for MSMEs, in an exclusive interview with Akanki Sharma

In what ways can technology adoption be the key for pharma manufacturing transformation? Tell us about the role played by NASSCOM CoE in this regard.

NASSCOM CoE is part of the 'Digital India' initiative of the Ministry of Electronics and IT, in collaboration with state governments, and is focussed on accelerating adoption of digital technologies in industries. We have built the largest ecosystem in the country to bring together enduser enterprises, solution providers and academia to cocreate solutions that can help in solving complex business issues. Pharma being a large industry is an important sector, both for global and Indian manufacturers. We understand that the challenges and needs vary with the size of the companies and our programmes are aligned to meet their requirements. In the past two years, we have

been running innovation challenges in healthcare and manufacturing sectors where large enterprises share their complex problems for which deep-tech startups propose solutions. The winning startup works with the enterprise to deploy the solutions. We also have long-term industry partnership programmes in case an enterprise has multiple use cases for finding technology-based solutions.

For a pharma manufacturer, the quality of drugs and compliance with Global Manufacturing Practices (GMP) are the most essential. Pharma units need to focus not only on agile and integrated supply chain, but also on seamless operations to drive reduction in the use of raw material, human resources and the risk of lowquality products. Digitalisation has the potential to transform supply chain, boost productivity and improve manufacturing operations. It includes adoption of Industry 4.0 solutions for areas such as production, quality, compliance, procurement, logistics, R&D and workforce development. Digital solutions for paperless operations can digitise the data recording and generate insights from analytics to optimise processes. Condition monitoring of critical equipment prevents them from unwanted breakdowns. Computer vision-based quality inspection of drugs can highlight defects and missing drug in the packaging. Augmented Reality-based virtual plant visits can drive customer and partner engagements, in addition to AR/VR solutions helping in remote collaborations and workforce training. Smart warehousing and supply chain solutions provide drug monitoring, theft security and movement tracking solutions.

While building a smart manufacturing roadmap, what are the aspects that a pharma organisation must keep in mind? Give reasons to support your answer.

Digital roadmap defines the success of technology initiatives in an organisation. There are numerous examples where digital solutions have failed to create an impact, which makes leaders feel these don't work for them. However, the real cause of failures is lack of structured roadmap in bringing technology to the organisation. Many times, we have seen enterprises have deployed ad hoc solutions without thinking long-term and that's when problems take place. While building plans for smart manufacturing, we suggest enterprise to start with the digital maturity assessment of the plant to understand current state of infrastructure, processes and organisation structures to support future growth. These findings are then mapped to cost structure of the enterprise and business objectives for next three-to five years. The recommendations that come from this exercise help in ensuring an integrated digital plan gets defined that will align with current challenges and future objectives. Design thinking approach can also be used to ensure proposed solution is human-centric and gets developed using agile methodologies.

NASSCOM CoE has launched the Smart Manufacturing Forum. Kindly give us details on the same. How is it going to benefit pharma manufacturers, especially Micro, Small and Medium Enterprises (MSMEs)?

In the new normal, where large pharma industries are moving towards digital-led growth, Micro, Small and Medium Enterprises (MSMEs) are falling behind and struggling to understand how technology can help. This disparity in technology adoption between large and MSME pharma units will create more challenges as supply chain needs global, Indian and MSMEs to work together. We met with lot of pharma MSME leaders and found lack of digital awareness is the biggest reason for the lack of technology adoption. Seeing the gaps between MSME and large pharma companies increasing, we launched the Smart Manufacturing Forum to make 100 MSMEs digital, so that they can become role models and inspire other MSMEs to replicate their success. Through this initiative, we aim to address the awareness, accessibility and affordability challenges that manufacturing enterprises face in technology adoption.

Smart Manufacturing Forum will help enterprises through skill and capacity building, hand-holding for digital journey, and branding and market reach.

What are the various digital skills that are required for smart manufacturing? Tell us how this forum will help in this regard.

The skills needed the most are understanding the applications of digital technologies to improve manufacturing productivity and efficiency. Manufacturing workforce don't need to know how to develop the applications, but they should be able to identify areas where technologies can help. The good part is it is not so difficult to learn, considering we have domain skills already available with the workforce.

The Smart Manufacturing Forum will help to develop digital awareness across all levels of an organisation.

These include interactive master classes for business and functional leaders and capability building sessions for managers. A knowledge bank comprising case studies, research reports, webinars and thought leadership sessions is made available to forum members with round the-clock access.

Skill building needs to be followed by solution adoption. How do you plan to provide handholding to pharma MSMEs looking to make their plants smarter?

We are keen to have forward looking pharma MSMEs to be part of the forum, as we would like to work with them to make them digital champions. This will happen through handholding that includes digital maturity assessment for understanding gaps in current processes and identifying opportunities for saving costs. Post this, we will conduct design thinking workshops by bringing together leadership and workforce to define the challenges, along with possible solutions. The outcome will enable us to build technology roadmap for MSMEs for which implementation will be done through co-creating solutions along with deep-tech startups. Our team will connect with both MSME team and startups to define requirements and oversee the implementation. The objective of our handholding is to create success stories that show that productivity and efficiency in plants can also be improved through software and give confidence to more MSMEs. We will also be inviting MSME leaders to present their success stories at the national level and give them a chance to establish themselves as thought leaders.

What are the current manufacturing trends in pharma MSME? How will these evolve in the future when compared to today's scenario?

Manufacturing in pharma MSMEs is currently being driven by regulatory and compliance requirements. Majority of the MSMEs are manufacturing drugs for exports, and, hence, for them, processes to align with certifications and the quality are of prime importance. We are making world-class drugs irrespective of whether they are produced in large or small plants, but the bigger question is - are manufacturing practices in small plants cost efficient? The answer is a big 'no.' While we have automation in place in every small pharma unit with processing equipment, processes are still manual. Records are maintained in registers, as not all units have ERP systems available, the inspection process is manual. All of these lead to inefficiencies as historical data is not available for analysis, inventory levels are high and there is a huge dependence on worker skills for doing quality inspection. These systems will not work in the long run as we need to be cost-competitive to operate in a global environment. Future systems will need to be integrated where man and machine talk to each other through data, and for this to happen, we need digital infrastructure. R&D is another area where small pharma units will need to invest and that cannot happen without technology adoption.

Source: Express Pharma, June 2022

● ● ●

NATIONAL NEWS

Paracetamol & 15 other drugs may be allowed to be sold 'over the counter' without prescription

NEW DELHI: With an aim to increase accessibility of commonly used medicines like paracetamol, diclofenac, nasal decongestants and anti-allergics, the government is set to allow sale of 16 such medicines as over-the-counter (OTC) products that can be sold without prescription from a doctor. The health ministry has issued a gazette notification proposing changes to Drugs Rules, 1945, to bring these products under Schedule K of the law, allowing the "drugs to be sold OTC by retail under valid licence".

The 16 medicines include antiseptic and disinfectant agent, Chlorohexidine mouth wash used for treatment of gingivitis, Dextromethorphan Hydrobromide Lozenges for cough, anti-bacterial acne formulation, anti-fungal creams,

nasal decongestants, an analgesic cream formulation and anti-allergy capsules, among others.

While the proposed changes will give legal sanctity to sale of medicines that aren't toxic without prescription, it will also ease their accessibility.

However, OTC sales will be allowed with certain conditions. For instance, the maximum duration of treatment or use shouldn't exceed five days and that if the symptoms don't resolve, the patient should consult doctors. The ministry has sought comments from stakeholders within a month.

Source: TNN, 07.06.2022

● ● ●

IDMA BULLETIN SUBSCRIPTION FORM

Date : _____

To
The Subscription Department
Indian Drug Manufacturers' Association ,
102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai – 400 018, India.
Email: admin@idmaindia.com /accounts@idmaindia.com / Web: www.idma-assn.org

Kindly enter my subscription to **"IDMA Bulletin".**

The details are as follows:

Name of the subscriber ……

Current institutional attachment ……

Designation ……

Delivery Address ……

City …… Pin code ……State ……

Country ……Phone no. (with STD/ISD code) ……

E-mail address ……

Subscription details

Subscription Period: One year

Subscription Type: India / Foreign

Subscription starts from: Month …… Year……

Payment details

Cheque No …… Dated …… Drawn on ……

Amount ……Date: ……

Signature of the subscriber

Annual subscription rates:

India (INR)

Members	Government Research/Educational Institutions	Non-Members
1000	2000	4000

Overseas (US$) :-

Individual
USD 400

Kindly note: *IDMA Bulletin* is Published on 7th, 14th, 21st and 30th of every Month.
(IDMA GSTIN:27AAATI3594D1ZO)

- Subscriptions are for calendar year only
- Please return the filled form to the above mentioned address.
- Cheque should be issued in favour of "**Indian Drug Manufacturers' Association",** payable at Mumbai.
- Please allow at least two weeks for commencement of new subscription.
- Claims for missing issues can be made only within fifteen days of publication

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

KINDLY NOTE:

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association".***

  For RTGS/NEFT: Name: BANK OF BARODA, **Branch:** Worli, **Name of Account Holder:** INDIAN DRUG MANUFACTURERS' ASSOCIATION, **Account No.** Current A/c 76080200000242, **IFSC :** BARB0DBWORL **MICR CODE :** 400012332
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, "A"-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018.Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723
Email: **admin@idmaindia.com/publications@idmaindia.com,** Website: **www.idma-assn.org / www.indiandrugsonline.org**

IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  The RTGS details are as follows:- BANK: BANK OF BARODA
  Account Name : ***Indian Drug Manufacturers' Association,*** *Bank A/c No. : Current A/c* ***76080200000242***
  Bank : ***BANK OF BARODA,*** *Branch Address : Worli Branch, Mumbai-18,* ***IFSC : BARB0DBWORL***
  MICR CODE : 400012332
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Melvin Rodrigues — Cell: +9821868758 (Email: actadm@idmaindia.com)/
Geeta Suvarna — — Cell: +9820161419 (Email: publications@idmaindia.com)

PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org/www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.06.2022

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**