ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

ENCOMPASSING ICH, WHO AND FDA REQUIREMENTS AND BEST INDUSTRY PRACTICES

IN COLLABORATION WITH

INDIAN DRUG MANUFACTURERS' ASSOCIATION

CAMPUS: ACHARYA COLLEGE, BANGALORE

ACHARYA INSTITUTES

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

SUCCESSFUL CANDIDATES WILL BE AWARDED AN INTERNATIONALLY RECOGNISED CERTIFICATION FROM NSF INTERNATIONAL AND IDMA.

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'. Brexit, Trump – 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. Participants will learn best-in-class practices and apply them in practical problem solving and real-life case studies. They will learn by doing.

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

This advanced education program covers best industry and regulatory practices presented by world-class tutors with 35 years of hands-on experience. It is designed for companies who aspire to be the best and who want a secure future.

WHY CHOOSE NSF?

NSF's Advanced Program in Pharmaceutical Quality Management is taught by world leaders in PQM. Based in the UK, NSF (previously David Begg Associates) 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

Those attending this program will gain the skills and knowledge to help their companies 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. One module takes place every other month. Training takes place in Bangalore at the beautiful campus of Acharya College. 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
- One-on-one mentorship and guidance from course tutors
- A written assessment to complete for each module

COURSE MODULES

In each module we will develop your leadership skills to prepare you and your companies to succeed. Case studies and problem-solving exercises will be used to improve your skills in risk-based decision making, communication, crisis management, problem solving and change leadership. Best-in-class practices relating to data integrity, process validation, technology transfers and more will also be covered.

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

Module One: Pharmaceutical Quality Management Systems – Best Industry Practices

Tutors: **Mr Martin Lush and Mr Robert Hughes**

- How to ensure your QMS 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 QMS -- who must do what
- The essentials of data integrity
- 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 John Johnson and Mr Robert Hughes**

- 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
- Deviation management: How to ensure your system:
  - Prevents repeat deviation incidents
  - Is simple, fast and effective
- CAPA management
- Investigation skills, instructions and report writing skills


Module Three: Human Factors – Getting People to Follow the Rules

Tutors: **Mr Martin Lush and Mr Robert Hughes**

- 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 organization 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)

Module Four: Transforming Data into Information – The Practical Application of Statistics to Transform Your Business

Tutors: **Dr Peter Gough and Mr Chris Harris**

- Summarizing and visualizing 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: **Dr Peter Gough and Mr Bruce Davis**

- 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

COURSE FEE:

NSF and IDMA have worked together to offer this course as a service to the industry. The course fee is being charged to cover the expenses related to design, delivery and administration of the course. The course is offered for a cluster of 30 to 40 delegates to distribute the cost. The course fee is approximately 8,100 GBP + 15% service tax + actual travel and stay expenses.

This type of program would typically cost 150,000 GBP for a company to engage the faculty for 40 tutor days for in-house training compared to 10,000 GBP for the entire program.

Next Steps: Your Call to Action

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

- View our free 30-minute webinar 'NSF and IDMA Advanced Program in Pharmaceutical Quality Management' by Mr Martin Lush, President, NSF Health Sciences on our website: **http://www.nsf.org/info/pbwebinars**
- Contact Martin Lush at **martinlush@nsf.org**

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NSF INTERNATIONAL

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