



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



INDIAN DRUG
MANUFACTURERS'
ASSOCIATION

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

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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



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)





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
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