RUBIZON®

ABLE. CAPABLE. FUNCTIONAL

CORPORATE TRAINING

BIOLOGICS | BIOSIMILARS | PHARMACEUTICALS

REACH US:

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WHO WE ARE

We are Chemistry, Manufacturing and Control (CMC) experts for pharma & biopharma industries. Our pragmatic solutions are in line with ICH guidelines for developing robust and consistent drug manufacturing process which ensures consistent product quality & patient safety.

WHAT WE DO

We share state of the art experience in Quality by Design solutions w.r.t biologics, biosimilars and pharmaceuticals. Our proven tools have helped industries to increase the success rate at R&D and manufacturing. We understand the complexities of upstream, downstream, formulation, product & process characterization, analytical methods, scale-up, technology transfer and manufacturing.

MODULES

Our training portfolio has 5 main modules, which are key components in drug manufacturing. All modules are designed to meet the current industry requirements and are in line with ICH guidelines. These modules help industries to:

- Enhance employees skill sets
- Significantly reduce development & manufacturing cost
- Achieve global quality standards
- Meet the project time line

The designed modules are:

- Research & Development
- Analytical & Characterization
- Manufacturing
- Quality management
- Documentation

MODULE 1

Research & Development

Due to increased global competition, R&Ds are expected to deliver cost effective and robust processes in time. This includes designing experiments by using statistical software which saves thousands of cumulative man hours and resources. It's critical to know scale up factors for successful transfer of technologies from lab to pilot and pilot to manufacturing.

INDEPENDENT TOPICS

- Design of Experiments: Tools, statistical designs and analysis of data
- Industrial scale up
- Technology transfers
- Process characterization

TARGET AUDIENCE

- Process scientists: Upstream/Downstream/ Formulation
- Scale up team
- Method development team

KEY LEARNINGS

- Usage of software tools such as JMP, Minitab, MODDE etc
- Screening designs (Full/fractional factorials, RSM, Taguchi, D-optimal etc.)
- Execution and building mathematical models
- Risk assessment
- Scale dependent & independent factors
- Scale down model qualification
- Determination of CPPs and PARs
- Design space
- Implementation of lab scale process to manufacturing

EXPECTED OUTCOME

- Predictive process
- Effective tech transfers
- Ease in deviation management
- Troubleshooting MFG challenges
- Ease in post approval changes

DURATION

DAYS: 3, 5 or customized based on requirement

MODULE 2

Analytical & Characterization

Analytical methods and characterization tools are certainly one of the most critical parts from drug discovery till commercial manufacturing. All product and process related impurities must be detected and quantified during development stages

INDEPENDENT TOPICS

- Product characterization
- Data acquisition and analysis from instruments such as MS, CD, Fluorescent microscopy, HPLC, DLS, FTIR, AAS
- Method characterisation
- Method qualification and validation
- Method transfers

TARGET AUDIENCE

- Product characterization team
- Method development team
- QC individuals

KEY LEARNINGS

- Method development using DoE tools such as JMP/Minitab/MODDE etc
- Intact mass analysis
- Peptide fingerprinting
- Peptide/protein sequencing
- Characterization of PTMs
- Characterization of disulphide linkages
- Secondary structure analysis
- Statistical establishment for qualification, validation and transfers

EXPECTED OUTCOME

- Safe and effective product
- Establishing correlation between orthogonal methods for product quality
- Successful transfers of qualified methods
- Reduced time for method development

DURATION

DAYS: 3, 5 or customized based on requirement

MODULE 3

Manufacturing

Commercial success is possible when manufacturing and cross functional teams produce safe and effective product. Regulatory agencies across the globe would also like to know batch histories to ensure patient safety. It's inevitable for manufactures to demonstrate the control over the process in time. Our indigenous modules help industries to deduce short and long term control limits.

INDEPENDENT TOPICS

- Process validation
- Cleaning validation
- Equipment validation
- Leachable and extractable
- Hold time stability
- Continuous process verification
- Annual product quality review

TARGET AUDIENCE

- Process scientists
- Production team
- Method development team
- MSAT and Pilot plants

KEY LEARNINGS

- Control strategy
- Validation know how
- Process performance index (Ppk)
- Process capability index (Cpk)
- Control charts
- Response to shifts and trends
- Action and alert points
- Stability protocols and report analysis

EXPECTED OUTCOME

- Successful validation campaign
- Manufacturing process 'in-check'
- Confident dossier application

DURATION

DAYS: 3, 5 or customized based on requirement

MODULE 4

Quality management

It's a must for any manufacturer to adhere to pre-defined quality management system and policies. The standard procedures should be inculcated within the system and must be reviewed periodically to meet current regulatory norms. Below topics are designed to provide necessary learnings which ensure good QMS.

INDEPENDENT TOPICS

- Recording and archiving raw data
- ICH guidelines for effective manufacturing
- Change controls
- Managing OOS/OOT/CAPA
- Deviation management

TARGET AUDIENCE

- Process scientists
- Production team
- Method development & characterisation team
- MSAT and Pilot plants
- QA & QC individuals

KEY LEARNINGS

- ICH products: Quality, Safety, Efficacy and Multidisciplinary
- QMS methodology
- Strategies for OOS/OOT/CAPA management

EXPECTED OUTCOME

- Successful audits
- Safe and effective product
- Minimize batch failures
- More number of Golden Batches
- Confident dossier application

DURATION

DAYS: 3, 5 or customized based on requirement

MODULE 5

Documentation

Its must for any organization to have a well-defined documentation system. Effective documentation ensures ALCOA (Attributable, Legible, Contemporaneously recorded, Original and Accurate data). The objective of each document must be clearly defined and appropriate training should be provided to all relevant stakeholders.

INDEPENDENT TOPICS

- Documentation: SOPs, SAMs, Training records, development reports, BMRs, technology transfer documents and technical reports
- Effective use of tools such as MS OFFICE
- All types of logs and registers
- Art of technical writing

TARGET AUDIENCE

- All teams who are actively involved in product development and manufacturing

KEY LEARNINGS

- Preparation of critical documents
- Protocols and reports
- Advanced MS Word, MS Excel and MS PowerPoint
- Key elements of specific technical documents

EXPECTED OUTCOME

- No operational ambiguity
- Ease in root cause analysis
- Ease in communication
- Confident in dossier applications
- Smooth audits with minimal or no observations

DURATION

DAYS: 3, 5 or customized based on requirement