QUALITY AND PROJECTS

PHARMACEUTICAL QUALITY SYSTEM

Quality Pharmaceutical Management is a strategic activity, that goes further than traditional quality systems in order to transform itself in a real critical factor of business and companies development.

LEGISLATION UPDATE
- EMA, FDA, AEMPS, PIC/S, ICH, PDA, ISPE

QUALITY ASSURANCE
- Corporate quality strategies designing
- Risk Management integration
- Internal audits (process, procedures, documentation)
- Regulatory inspections (AEMPS, EMA, FDA)

QUALITY SYSTEM
- Change controls. OOS
- Incidences management. CAPA
- Operational documentation Optimization and simplification
- SOPs, instructions, manufacturing and packaging master batch records

PRODUCTIVITY AND COMPETITIVENESS
- Productivity implication, KPIs for quality.

INDUSTRIAL PROJECTS

Industrial Projects Management is one of the most complex activities where values as for example quality, productivity and business profitability must be considered.

PHARMACEUTICAL ENGINEERING PROJECTS
- Industrial Engineering, viability studies, facilities design.
- Conceptual design, basic engineering, detailed engineering.

PERSONAL DEVELOPMENT PROJECTS
- Leadership, communication, development and personal motivation.
- Information management. Knowledge management.

EXPERTS AND TECHNICIANS OUTSOURCING
- Expert consultants with full time dedication into specific projects.

LEAN MANAGEMENT & GMPS
- Productivity improvement
- Reduction defects
- Resources optimization
- Delivery deadline improvement

LEAN MANAGEMENT PROJECTS
- 5S organization and cleanliness
- TPM Total Productive Maintenance
- SMED Rapid format changes
- VSM Flows and deadlines
- Cells in U Productivity
- 8D claims
- 5W root cause
- KAIZEN Progressive improvement
OPTIMIZATION OF PROCESSES AND VALIDATION

PROCESSES OPTIMIZATION

Because **efficiency of industrial area** is critical for the companies competitiveness.

MANUFACTURING PROCESSES IMPROVEMENT

PRODUCTS FORMULATION IMPROVEMENT

**GENERIC PRODUCTS**

- Solution for manufacturing issues: FF solid and liquid
- Cost reduction – Industrial efficiency
- Processes optimization – simplification
- Manufacturing methods Optimization
- Formula optimization: regulatory impact

**NEW PRODUCTS**

- New formulas with added value
- Line extensions
- Oral forms aromatization

**PHARMACEUTICAL DEVELOPMENT**

- Industrial scale: lot size, large volume production
- Production transfer: new products, plants optimization
- Team evaluation: different technologies
- Excipient evaluation: manufacturers, particles size
- Dossier evaluation: external and internal
- Stability studies: definition and protocols, evaluation of results

QUALIFICATION AND VALIDATION

Qualification and **validation activities** are the tool for demonstrating a proper adequacy of facilities and equipment, and the suitability of processes.

**VALIDATION PROCESSES MANAGEMENT AND SUPERVISION**

- Master Plan Validation (MPV) design
- Specific validation plans design
- Risk assessment
- Specifications documents: URS, FS, DS
- Protocols design: FAT, SAT, DQ, IQ, OQ, PQ

**QUALIFICATION ACTIVITIES**

- Qualification Matrix design
- Qualification of rooms and manufacturing facilities
- Qualification of critical services (HVAC, PW, WFI, CIP/SIP, gases)
- Qualification of production equipment (manufacturing and packing)
- Qualification of analytical tools

**VALIDATION ACTIVITIES**

- Manufacturing processes validation
- CQAs, CMAs, CPPs, Stages 1-2-3
- Process Performance Qualification (PPQ)
- Permanent monitoring [CPV]. Capacity studies.
- Statistical graphics of control. AQL. Statistical sampling.
- Cleaning processes Validation
- Design of process, toxicological limits, PDE, cleaning agents
- Analytical methods Validation
- Computing systems validation: GAMP5, ERP, SCADAs, PLCs, LIMS
Our clients speak for us

Official agencies and bodies

Pharmaceutical laboratories

Biotechnology, cell therapy, transplants, regenerative medicine, cro’s
Since 2006
Training for inspectors
Spain, Europe, South America
AEMPS, Cataluña, Valencia, Castilla y León, Islas Baleares

More than 400 customers
More than 550 industrial projects
INTERNAL AUDITS

GLOBAL
Compliance with GMP Standards
Quality system performance evaluation
Due Diligence

SPECIFIC

BY SYSTEMS
• Quality system
• Material system
• System facilities and equipment
• Production system
• Conditioning and labeling system
• Laboratory control system
• Distribution system

BY AREAS
• Warehouses
• Manufacturing
• Packaging
• Quality control
• Maintenance

BY CRITICAL ELEMENTS
• Process Critical parameters
• Critical quality attributes of product

DATA INTEGRITY
• Data generated and stored on paper
• Electronic data
• Data of suppliers and contract manufacturers

VALIDATION AND QUALIFICATION
• Validation documentation (VMP, protocols, reports, etc.)
• Results and reports review
• Processes ongoing verification

ELEMENTS OF THE PHARMACEUTICAL QUALITY SYSTEM
• Change control
• Deviations and CAPA management
• Product quality and process efficiency
• Indicators and monitoring by management
• Training and certification of personnel
• Risk management
• OOS, OOT
EXTERNAL AUDITS

AUDITS TO RAW MATERIALS SUPPLIERS
Joint Audit and Shared Costs Scheme

SCHEDULED EXTERNAL AUDITS PLANS
Audits scheduled by geographical areas
• To identify and organize suppliers in the same area

Audits scheduled by strategic suppliers
• To identify laboratories interested in the same supplier

CUSTOMIZED EXTERNAL AUDITS
Specific supplier audits
Specific raw material Audits
Manufacturing process Audits
Analytical development Audits

SAVINGS OPTIONS
Share performance costs
• Shared audit costs

Share travel expenses by geographical areas
• Shared travel costs

TYPES OF AUDITS
Audits to API manufacturer
Audits to excipient manufacturers
Audits to manufacturers of primary packaging materials
Audits to manufacturers of secondary packaging materials
Audits to contract drug manufacturers
Audits to Analytical service supply
Audits to raw materials and medicines distributors
Audits to API and drug transportation agency
Audits to GxP software developer
Audits to contract warehouse
PREPARATION FOR RECEIVE REGULATORY INSPECTIONS

Training and coaching to key personnel
Key points to control when receiving an inspection
Assistance during the inspection
Assistance in the preparation of the response to the inspection

EXPERT AUDITORS

The ASINFARMA AUDITS audit team has proven experience in conducting international audits in compliance with GMP requirements.

CONFIDENTIALITY GUARANTEE
ASINFARMA MICROBIOLOGY OFFERS TECHNICAL SUPPORT IN PHARMACEUTICAL AND COSMETIC MICROBIOLOGY:

M ICROBIOLOGY APPLIED TO QUALITY ASSURANCE DEPARTMENT

• Audits
• Pre-audits for inspection preparation
• Support in microbiology investigations and corrective and preventive actions (CAPA) definitions
• Specialized training
• Aseptic Process Simulation (APS) validation

M ICROBIOLOGY APPLIED TO PRODUCTION DEPARTMENT

• Contamination Control Strategy
• Risk assessment
• Aseptic process evaluations
• Personnel and material flow definitions
• Cleaning and disinfection program
• Cleanrooms qualifications
• Qualification of personnel that operates in aseptic processes
• Sterilization process validation (saturated steam, ethylene oxide, dry heat, filtration, ionizing radiation (γ, β, ...)
• Equipment cleaning and disinfection process validation
MICROBIOLOGY APPLIED TO QUALITY CONTROL DEPARTMENT

- Good Laboratory Practices (GLPs)
- Laboratory designs
- Microbiology methods for non-sterile products development and validation (raw materials, bulk, finished products, primary packaging material, ...)
- Microbiology methods for sterile products development and validation
- Methods for endotoxin determination development and validation
- Development and validation of methods for assessing active ingredients with biological activity (antibiotics)
- Preservative agent efficacy
- In use stability testing
- Microbial identification strategies
- Monitoring program design: Viable particles, non-viable particulates, compressed gases, water for pharmaceutical industry,...
- Equipments qualification (autoclave, isolators,...)
IN COMPANY TRAINING

DIFFERENTIAL FEATURES

CUSTOMIZED FOR DIFFERENT LEVELS
- Direct labour employees
- Supervisors, coordinators and technicians
- Heads, bosses, managers and directors

FLEXIBLE MODALITIES
- Face-to-face
- Live virtual

CONTINUING EDUCATION
- General content of the GMP
- Special content on critical topics

GMP TRAINING
Initial training
- Welcome interactive online course
- GMP introductory courses

SPECIFIC TRAINING FOR THE JOB
- Training in operational techniques and procedures
- Training in hygiene and good practices

SPECIALIZED TECHNICAL TRAINING
- Update on new regulations
- Lean Management
- TPM

LEADERSHIP, MOTIVATION AND SKILLS TRAINING

LEADERSHIP STRATEGIES
- Oriented to supervisors, coordinators and technicians
- Oriented to managers, bosses, directors

MOTIVATION ACTIVITIES
- Direct labour employees
- Supervisors, coordinators
- Technicians and managers

INTERACTIVE GROUP ACTIVITIES
- Team building
- Values awareness
- Expansion of competencies

HIGH PERFORMANCE EQUIPMENTS
- Teamwork techniques
- Conflict management techniques

PERSONALIZED COACHING
- Skills development for key people
OPEN TRAINING FOR THE WHOLE INDUSTRY

ANNUAL PROGRAM OF SPECIALIZED TRAINING SEMINARS

SINCE 2009 (13TH EDITION IN 2021)

Specialized updating for directors, managers, supervisors and technicians who carry out their activities in the industrial area, where being able to manage new possibilities and expectations is not only a regulatory requirement, it is a true factor of success and a matter of business survival.

The seminars are held in Barcelona and Madrid

Between 15 and 25 seminars each year

More than 150 seminars

More than 170 teachers

More than 1,750 participants

All the news in national and international pharmaceutical legislation

Permanent technical updating on regulatory requirements and quality systems

SOME OF THE MAIN THEMES DEVELOPED

1. Practical application of quality risk management applied to the entire set of pharmaceutical industrial activities
2. Complete specialization programs in the new validation strategies
3. Optimization of the effectiveness and efficiency of the pharmaceutical quality system
4. Microbiological contamination control, good microbiology practices, aseptic processes, environmental monitoring program
5. Data Integrity, human error, deviation investigation, CAPA, change control, KPIs
TOPICS RELATED TO VALIDATIONS:
1. Design of the Validation Master Plan (VMP)
2. Validation / qualification of facilities, services and production equipments
3. Qualification of clean areas according to the new annex I of the GMPs
4. Process validation
5. Cleaning validation
6. Aseptic processes validation
7. Analytical methods validation
8. AqBD: Analytical Quality by Design
9. Analytical instruments validation
10. Computerized systems validation
11. Design and validation of spreadsheets
12. Aseptic Process Simulation - media fill
13. Design, qualification and monitoring of pharmaceutical water systems

TOPICS RELATED TO MULTIPRODUCT PLANTS:
14. Systems and procedures to avoid cross contamination
15. Toxicological limits in multiproduct pharmaceutical plants

GMP / BPM RELATED TOPICS:
16. Good Manufacturing Practices (GMP) and GMP Standards [PIC / S-FDA-EMA]
17. Sterile drug manufacturing [PIC / S-EMA]
18. Sterile drug manufacturing (New Annex I of the EUGMPs)
20. Preparation of the Site Master File required by OMS-PIC / S-FDA-EMA
21. Good distribution and supply practices. Supply chain control
22. GMPs in the manufacture of advanced therapy drugs
23. Annex II of the GMPs: Biological drugs. Advanced level
24. Part II of the GMPs: Active substances manufacturing. Advanced level
25. Serialization in the pharmaceutical industry
26. Implementation of a program to control elemental impurities. ICH Q3D.
27. Course on novelties in GMPs (last two years)
28. Risk management for pharmaceutical excipients
29. Quality of biotechnology products
30. Development and manufacture of active substances
31. Good agricultural and harvesting practices of medicinal plants for active ingredients

TOPICS RELATED TO GLP:
32. Preparation for GLP certification
33. Good Quality Control Laboratory Practices [GLP]
34. Optimize the management of the quality control laboratory. Updated with new EDQM standards
35. Effective Out of Specification Results Management [OOS]
36. Drug stability tests
37. Work procedures in the GLP laboratory
38. Data Integrity in the GLP laboratory
39. Statistical treatment of stability data
40. Qualification of analytical instruments

TOPICS RELATED TO AUDITS:
41. How to conduct an internal audit [GMP auditor approach]
42. How to receive an internal audit [GMP audited approach]
43. How to perform an external supplier audit [GMP auditor approach]
44. Homologation and validation of active ingredients suppliers
45. Homologation and validation of medicinal plants suppliers. New!
46. How to receive a pharmaceutical inspection [GMP audited approach]
47. How to receive an external client audit [GMP audited approach]

TOPICS RELATED TO STRATEGIC MANAGEMENT:
48. Regulatory flexibility and GMP of the XXI Century
49. Quality risk management [Quality Risk Management - ICH Q9]
50. Pharmaceutical Development [ICH Q8]
51. Pharmaceutical Quality System [ICH Q10]
52. Productivity and industrial organization by processes
53. Practical course on risk management: Risk Ranking and Filtering. Designed with your needs!
54. Risk management workshop: FMEAC
55. Risk management workshop: HACCPs
TOPICS RELATED TO THE QUALITY SYSTEM:
56. Quality assurance as a productivity tool
57. Investigation of deviations, CAPAs and change controls. Comprehensive vision.
58. Investigation of OOSs
59. Investigation and reduction of human errors
60. Investigating Data Integrity Deviations
61. Tools for root cause analysis
62. Corrective Actions and Preventive Actions System (CAPA)
63. Product life cycle management. Exchange Control according to ICH Q12
64. Annual Product Review (APR / PQR)
65. Periodic review of quality system management
66. Simplified drafting of Standard Operating Procedures (SOP)
67. The Data Governance System. Data Integrity Managerial and technical level
68. Statistical methods for process monitoring

TOPICS RELATED TO CLINICAL TRIALS AND PHARMA-COVIGILANCE:
69. Good clinical practice of the European Union
70. Clinical trials of bioequivalence
71. Manufacture of investigational drugs

TOPICS RELATED TO PACKAGING MATERIALS:
72. GMPs in the manufacture of primary conditioning material. ISO 15378.
73. Ecodesign

TOPICS RELATED TO INDUSTRIAL MICROBIOLOGY:
92. Contamination control and environmental monitoring program
93. Cleaning, disinfection, sterilization and decontamination processes
94. Industrial Microbiology
95. Microbiology for non-sterile industrial processes
96. Contamination Control Strategy (CCS): New Annex 1
97. Isolator technology for contamination control
98. Aseptic Process Simulation (APS): Strategies and Validation
99. Monitoring processes and systems for viable particles. Environmental monitoring programs (ISO 17141)
100. Microbiology in the quality control laboratory
101. Root cause investigations of microbiological excursions
102. Pharmaceutical water systems

TOPICS RELATED TO LEAN MANAGEMENT:
90. Implementation of lean management
91. Implementation of lean management tools

SPECIFIC GMP MODULES FOR OPERATORS AND ANALYSTS:
74. Finished Product storage areas
75. GMPs in sterile drugs manufacturing
76. GMPs in packaging
77. GMPs in packaging with an FDA approach
78. GMPs analysts of the Quality Control laboratory
79. Sterile area aseptic practices

80. GMPs in the manufacture of oral medicines
81. GMPs in engineering and maintenance operations
82. Annex II of the GMPs: Biological drugs
83. Part II of the GMPs: Manufacture of Active substances.
84. Basic Data Integrity for operators and analysts
85. Raw Materials storage areas

TOPICS RELATED TO BIOSECURITY:
86. Biohazard Analysis in industrial facilities
87. Implementation of a Biosecurity plan in biological medicine facilities
88. Practices in classified biosafety areas

GDP RELATED ISSUES
89. Implementation of good distribution practices