GRUP ASINFARMA

ASINFARMA
ASESORÍA INDUSTRIAL

ASINFARMA
GESTIÓN DE CALIDAD

ASINFARMA
MICROBIOLOGÍA INDUSTRIAL

ASINFARMA
FORMACIÓN ESPECIALIZADA

A quality strategy aimed at taking care of your business

Our clients speak for us

GRUPO ASINFARMA

Official agencies and organizations

agencia española de medicamentos y productos sanitarios · Generalitat de Catalunya Departament de Salut · Agència Valenciana de Salut · Farmacéuticos Consejo General de Colegios Farmacéuticos · Gipuzkoako Farmazialariak / Farmacéuticos de Gipuzkoa · Energiaren Euskal Erakundea Ente Vasco de la Energía · Servizo Galego de Saúde

COLOMBIA — invima

CUBA — CECMED

URUGUAY

CHILE

REP. DOMINICANA — Gobierno de la República Dominicana, Salud Pública

Pharmaceutical laboratories

Novartis · gsk · Merck · Sanofi · MSD · Boehringer Ingelheim · Bayer · almirall · Grifols · B Braun · Esteve · cinfa · Normon · Reig Jofre · Rovi · Uriach · ferrer · Fresenius Kabi · Alcon · Sandoz A Novartis Division · Solvay · Intervet Schering-Plough Animal Health · Wyeth · SmithKline Beecham · FAES FARMA · Famar · Baxter · BD Advancing the world of health · P&G Health · Lilly · McNeil a Johnson & Johnson company · Menarini group · Farmasierra Laboratorios Calidad e Innovación · Alcalá Farma · Alter · Hipra · Italfarmaco · Servier · s.p. veterinaria · 3P Biopharmaceuticals · Synthon · syva · TiGenix · Tollpharma · sylentis · Leon Farma · ADL BioPharma · Air Liquide · Alchemy International Services

ALK Abelló · Schering-Plough · teva · Zendal · Nieffe Medical · Biofabri · CZ Veterinaria · Diafarm Laboratorios · Diater · Dr. Torrents Laboratorio Farmacéutico

Durban Laboratorios · Praxis Pharmaceutical · vilardell · Ordesa · Galenicum · Vall Companys · CTC · Combino Pharm · Laboratorios Eran · Leo

Invent Farma · Aldo-Unión · Seid Lab · inmunotek · Super's Diana · cenavisa · Iteve · Mikrobiomik rethinking microbiome · pharmadiet Veterinaria · Laboratorios Maymo

Laboratoires Quinton · Pharma Internacional · Laboratorios Llorens · neftis laboratorios · Sincrofarm Laboratorios · Laboratori Dau · VIR · Laboratorios Torlan S.A. · Biomat USA Grifols · Rubió

Lesvi Laboratorios · Genfarma farmácias · GP Pharm · ojuste · Karizoo · Kern Pharma · Labiana Pharmaceuticals · Lacer · Lainco, S.A. · Lamons · Liof Pharma

Lonza · Maverick Therapeutics · Mevet · farmalider Group · Laboratoris Feltor · OJER Pharma · Pharmaloop · Pierre Fabre · premiumlab · Reckitt Benckiser

León Pharma Laboratorio Veterinario · Chemo · Calier · Recipharm · Inibsa Laboratorios · Casen Fleet Laboratories · Asacpharma · Laboratorios Viñas · Viralgen · Gelos

Prasfarma · Unipharma Delivering Global Innovations · unolab manufacturing · URGO Invent & Care · arm healthcare delivering creativity · IMIM Institut Hospital del Mar d'Investigacions Mèdiques · Ovejero · Laboratorios Eurisko International Health · Haleon

Ascil Biopharm · Laboratorios Bilper Group · ITAI pharma · Siegfried · meiji Meiji Pharma Spain, S.A. · mAbxience From lab to life · cantabria labs Spain · iVascular therapies for living · curia

MÉXICO

Ophia Excelencia en oftálmicos · Liomont · Maver · pharmaservice

REP. DOMINICANA

Mallen · Rowe · Sintesis · Acromax Dominicana · sued Seguridad Terapéutica

COSTA RICA

Gutis

COLOMBIA

west · Tecnoquímicas · Procaps · Vitrofarma S.A. · Corpaul · DSM · ave · new stetic Piensa en tu salud · Aquifer · SCF Safety Comes First · Aquifar

URUGUAY

Megalabs · Urufarma · Libra

ARGENTINA

Raffo · Acromax Su salud nos mueve

CHILE

ECUADOR

ASOFARMA

PARAGUAY

Fapasa

Biotechnology, cell therapy, transplants, regenerative medicine, CRO's

Banc de Sang i Teixits · eurofins · vivotecnia · Probiserch · LVD Biotech · Gadea Biopharma · CIM Centro de Imagen Molecular · Hospital de la Santa Creu i Sant Pau · CMR[B] · Cellerix · Quesper R&D · VCN Biosciences · Digna Biotech · Zinereo Pharma · Zeltia · proteos · Farmaprojects · Crucell · Pharma Mar · biomar · TiGenix · Ixaka · Inmunal · Endor · Biosearch Life · TSF Transplant Services Foundation · Osakidetza · Nanotherapix · ZeClinics · Covidien · Proteomika · The Genhelix Group · midatech pharma · Praxis Pharmaceutical · Lonza · Biofabri · IDIFARMA · Exentia · Gaiker

CUBA

CIGB Centro de Ingeniería Genética y Biotecnología

COREA

Samsung Bioepis

Medical Cannabis

Bhalutek Hemp · bio hemp trade · Canamedics Labs · JBCapitalMarkets · Medical Plants Quality Cannabis · Cualin · Dana Agronomics · Hemp Solution Europe · Hikurangi · Coacchella Dreams · Coronas Galicia · IG · D Medical Green · Mallorca Cultivos · Oliver Birch · Palmeera Farms · Project Verd del Mediterrani · Valuxury

URUGUAY

CPLANT

COLOMBIA

Clever Leaves · Groqo · NatuEra · Blueberries · Cannadrop · plena · mccn medcolcanna · PharmaCielo · Asociación Colombiana de Industrias de Cannabis Asocolcanna · BG Labs Colombia · Canapa · Purple Dragon · Tarkus Pharma Lab

Cosmetics, medicinal plants and medical devices

Puig · Nivea · Ubesol · Quesper R&D · Gal · enteMA Laboratorios · ISDIN · RNB · cotécnica · Nelly · Reval Cosmeceuticals Anjac · Iber Home · Optimal Care s.a. · Provital Group · Chemir s.a. · Lipotec · Institute BCN Barcelona · Bionorica · Dermo Pharmacie & Parfums · Laboratorios Almabe · Mozo-Grau · cmd · Feqpa · BDF Beiersdorf · Laboratorios Maverick · PCH Industries · Korott · Laboratorios Sparchim SL · eurofragance · Sendal · Natura Bissé Barcelona · Iber-Polen S.L. · URGO · Kinesia · Leventon · Keenwell · Derex Dermopharmacy Experts · Biomet · mesoestetic Pharma Group · cantabria labs Spain · Dentaid

Radiopharmaceuticals, immunology, diagnosis and reagents

Advanced Accelerator Applications · ALK · Biokit A Werfen Company · IRAB Institut de Radiofarmàcia Aplicada de Barcelona · probelte pharma · Inmunal · CRC Centre d'Imatge Molecular · Institut d'Alta Tecnologia PRBB · vircell Microbiologists · Roxall Group · Barnatron · Molypharma · Bial · Allergy Therapeutics Ibérica · BioSystems · Innoqua Toxicology Consultants · LETI

APIs and excipients

Chemo · Bionorica · Brenntag · Carburos Metálicos · Chemir s.a. · Crystal pharma · Fagron · Derivados Químicos · Micronizados Naturales, S.A. · Guinama · Inden Pharma · Inmet Garnick · nektium · Oxigen salud · Medinsa · Farmhispania Group · Calier · acofarma · Chemo · almirall · Urquima · Bioiberica · Moehs Fine Chemicals · Tradebe · IMCD · Ercros · vytrus biotech · medichem · lebsa · Provital Do Care · Frosst Iberica, S.A. MSD · Fontlab 2000 · aplicaps · Euromed · Suanfarma · Bioquim S.A.

Engineering, equipment manufacturers and service suppliers

Indus · CPQ Ingenieros · Pall · Grifols · Ingeclima · Ingelyt Ingeniería e Instalaciones · Inoxpa · MicroBios · charles river · MWV Meadwestvaco · Fundación Botín · Sabater Pharma · Labco Quality Diagnostics · Estrategia Dirección · gaez · Validated ID Always be yourself · tiselab Soluciones GMP · Kymos Pharma Services · Albian Group · CTC · Gerresheimer · WYS Witte y Sola · Idaglia · Cosmobot · Flova · Etories Técnicos · Autoetik · geiserPharma · TAE · Komtur Pharmaceuticals · sener · AM Animalia · GEicam Investigación en cáncer de mama · gruposifu Facility Services & Management · Eumedica · Dara Pharmaceutical Development

ASINFARMA

ASESORÍA INDUSTRIAL

"Because you can't do today's work with yesterday's methods and tools, and expect to stay in the market tomorrow"

INDUSTRIAL PROJECTS

The management of industrial projects is one of the most complex activities where principles of **quality, productivity** and **business profitability** must be considered.

1. INTEGRAL PROJECT MANAGEMENT (Turnkey)

Project Managers specialized in pharmaceutical projects

- Feasibility studies
- Project Master Plan
- Constitution of the project team
- Identification of stages and milestones
- Project management: Scope, activities, costs, times
- Execution and monitoring until closing

2. PHARMACEUTICAL ENGINEERING PROJECTS

Design, review and optimization of facilities, services, and equipment

- User Requirements Specification (URS)
- Systems risk analysis
- Design Review and Design Qualification
- Commissioning & Qualification
- Planning, testing and documentation
- Acceptance, certification and release for industrial use

Participation in engineering designs

- Adaptation of the engineering project to the pharmaceutical process
- Conceptual design
- Basic engineering
- Detailed engineering

3. IMPLEMENTATION OF LEAN MANAGEMENT AND GMP

We optimize, improve and reduce

- Optimization of productivity
- Optimization of human and material resources
- Improvement of delivery times
- Improvement of the definition of efficient KPIs
- Reduction of defects
- Reduction of costs

Our goal is a minimum improvement of 30% in all our projects. How do we get it?

By using the following tools:

- 5S: Order and cleanliness
- TPM: Total Productive Maintenance
- SMED: Single Minute Exchange of Die
- VSM: Value Stream Mapping
- U cells: Productivity
- 8D: Claims
- 5W: Root Cause
- KAIZEN: progressive improvement

OPTIMIZATION OF PROCESSES AND PRODUCTS

Because **the efficiency of the industrial area** is vital for the competitiveness of the company.

1. PHARMACEUTICAL DEVELOPMENT

Support to Galenic Development departments

- Development of new products and new processes
- Industrial scale-up and transfer to production
- Equipment evaluation: Different technologies
- Evaluation of excipients and APIs: Manufacturers, particle sizes
- Evaluation of dossiers: External and own
- Stability studies: Definition and protocols, evaluation of results
- Generation and evaluation of Development Reports

2. PROCESS IMPROVEMENT

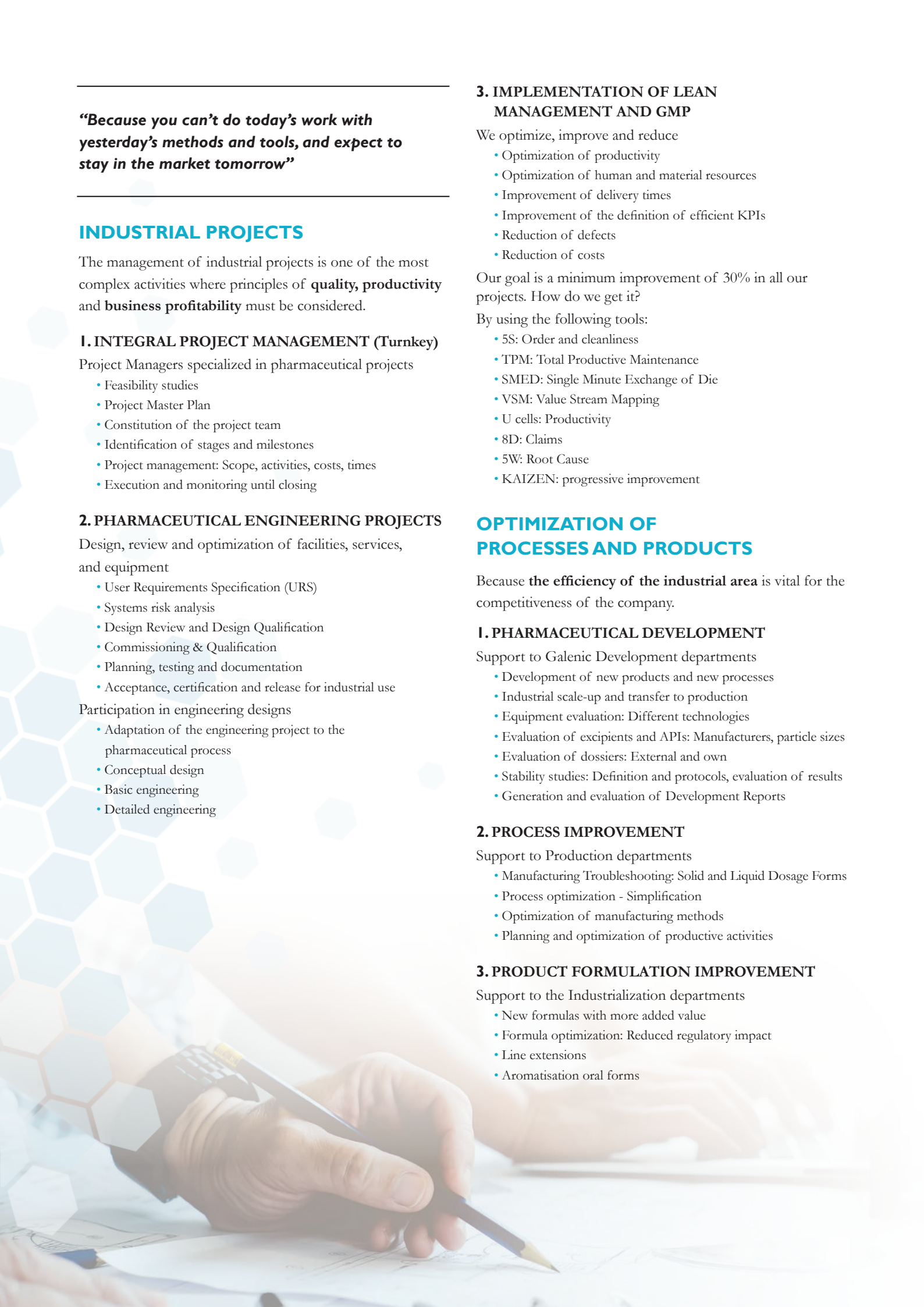
Support to Production departments

- Manufacturing Troubleshooting: Solid and Liquid Dosage Forms
- Process optimization - Simplification
- Optimization of manufacturing methods
- Planning and optimization of productive activities

3. PRODUCT FORMULATION IMPROVEMENT

Support to the Industrialization departments

- New formulas with more added value
- Formula optimization: Reduced regulatory impact
- Line extensions
- Aromatisation oral forms



QbD AND PAT IN PHARMACEUTICAL DEVELOPMENT

Because quality is neither controlled nor manufactured, **quality is designed.**

1. ADVICE AND SUPPORT IN THE IMPLEMENTATION

Support to the Development and Industrialization departments

- Support and training in QbD, ICH Q8 and PAT
- Risk assessments and analysis
- Design of Experimental Model (DoE)
- Support in the development of PAT processes

2. ADVICE AND SUPPORT IN THE EXECUTION

Direction and management of the implementation project

- Description of the QTPP (Quality Target Product Profile)
- Identification of CQAs (Critical Quality Attributes)
- Identification of CPPs (Critical Process Parameters) and CMAs (Critical Material Attributes)
- Carrying out the Risk analysis
- Design of Experimental Model (DoE)
- Evaluation of results and generation of the final report
- Support in the presentation of the registration dossier

QUALIFICATION AND VALIDATION

Qualification and validation activities are the tools to demonstrate the **adequacy** of facilities and equipment, and the **suitability** and **reliability** of processes.

1. MANAGEMENT AND SUPERVISION OF VALIDATION AND QUALIFICATION PROJECTS

Project Managers specialized in validation projects

- Design of the Qualification Matrix
- Design of the Validation Master Plan (VMP)
- Design of specific validation plans
- Risk assessment
- Specification documents: URS, FS, DS
- Protocol design: FAT, SAT, DQ, IQ, OQ, PQ

2. QUALIFICATION ACTIVITIES

Design of protocols and support in the execution

- Qualification of manufacturing rooms and facilities
- Qualification of critical services (HVAC, PW, WFI, CIP/SIP, gases)
- Qualification of production equipment (manufacturing and packaging)
- Qualification of analytical equipment and instruments

3. VALIDATION ACTIVITIES

Validation of manufacturing processes

- Stage 1: Process Design (CQAs, CMAs, CPPs)
- Stage 2: Process Qualification and PPQ (Process Performance Qualification)
- Stage 3: Continuous Process Verification (CPV)

Validation of cleaning processes

- Cleaning process design
- Toxicological limits, PDE
- Selection of cleaning agentsValidación de métodos analíticos

Validation of analytical methods

Validation of computer systems (GAMP5):

SCADAs, LIMS, Quality Managers, ERP

Validation of transport routes (GDP)

AVAILABLE SUPPORT

PROFESSIONAL FIGURES

- Project Managers experts in Project Management
- Executive consultants with full-time dedication to specific projects
- Multidisciplinary teams:
  - › Experts in Quality System and regulations
  - › Auditors
  - › Engineers
  - › Microbiologists
  - › Experts in the microbiological and physicochemical control laboratory
  - › Experts in galenic development
  - › Experts in the manufacture of sterile products
  - › Experts in aseptic processes

ACTIVITIES AND TOOLS

- Drafting and review of technical documentation
- Strategy design
- Protocol execution
- Specialized technical consultancy

ASINFARMA GROUP IN NUMBERS

Since 2006 › Spain › Europe › Latin America

- More than 400 client companies
- More than 600 industrial projects

TRAINING FOR INSPECTORATES

Spain

- AEMPS
- Catalonia, Valencia, Castilla y León, Balearic Islands

Latin America

- INVIMA (Colombia), CECMED (Cuba), DIGEMAPS (Dominican Republic), MS (Uruguay), MS (Chile), DIGEMID (Peru), COFEPRIX (Mexico)

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GESTIÓN DE CALIDAD

"A quality strategy aimed at taking care of your business"

PHARMACEUTICAL QUALITY SYSTEM

Pharmaceutical quality management is a strategic activity that goes beyond traditional quality systems to become a **true critical business and factor**

1. UPDATE OF REGULATIONS

National and international standards, directives and guidelines

- EMA, FDA, WHO, AEMPS
- PIC/S, ICH, PDA, ISPE

Regulatory compliance optimization projects

- Compliance assessment audits (Gap Analysis)
- Design of the remediation plan (CAPA Plan)
- Support to implement the CAPA Plan
- Support during regulatory inspection
- Support in the preparation of the response to the inspection

2. QUALITY ASSURANCE SYSTEM

Support to Quality Assurance departments

- Design and implementation of the pharmaceutical quality system
- Design of strategies and corporate quality policies
- Change Control Management
- Out Of Specifications (OOS) Management
- Management of Incidents, Deviations and CAPAs
- Data Integrity Strategies (paper systems and computer systems)
- Supplier Evaluation
- Design and review of qualification and validation strategies
- Development of the Site Master File (SMF)

3. RISK MANAGEMENT PROJECTS (QRM)

Effective implementation of the risk management process

- Risk assessment activities
  - › Hazard identification
  - › Use of risk analysis tools
- Risk control activities
  - › Mitigation plans
  - › Contingency plans
- Risk review activities
- Integration of risk management in the quality system

4. OPTIMIZATION OF THE DOCUMENTATION SYSTEM

Reorganization, integration and definition of documentary structures

- Optimization of flows from generation to document approval
- Optimization and simplification of operational documentation
  - › SOPs/SOPs, instructions
  - › Manufacturing and packaging guidelines

5. DESIGN OF INDICATORS

Product quality indicators

- Simplification of PQR (Product Quality Review) reports
- Continuous Process Verification and maintenance of the validated state
  - › Statistical analysis
  - › Process capacity studies (Cp, Cpk, Pp, Ppk)
  - › Statistical Process Control Charts
  - › Detection and trends analysis

Reports and indicators for management

- Design of KPIs (Key Performance Indicators)
- Implication in productivity
- Quality costs

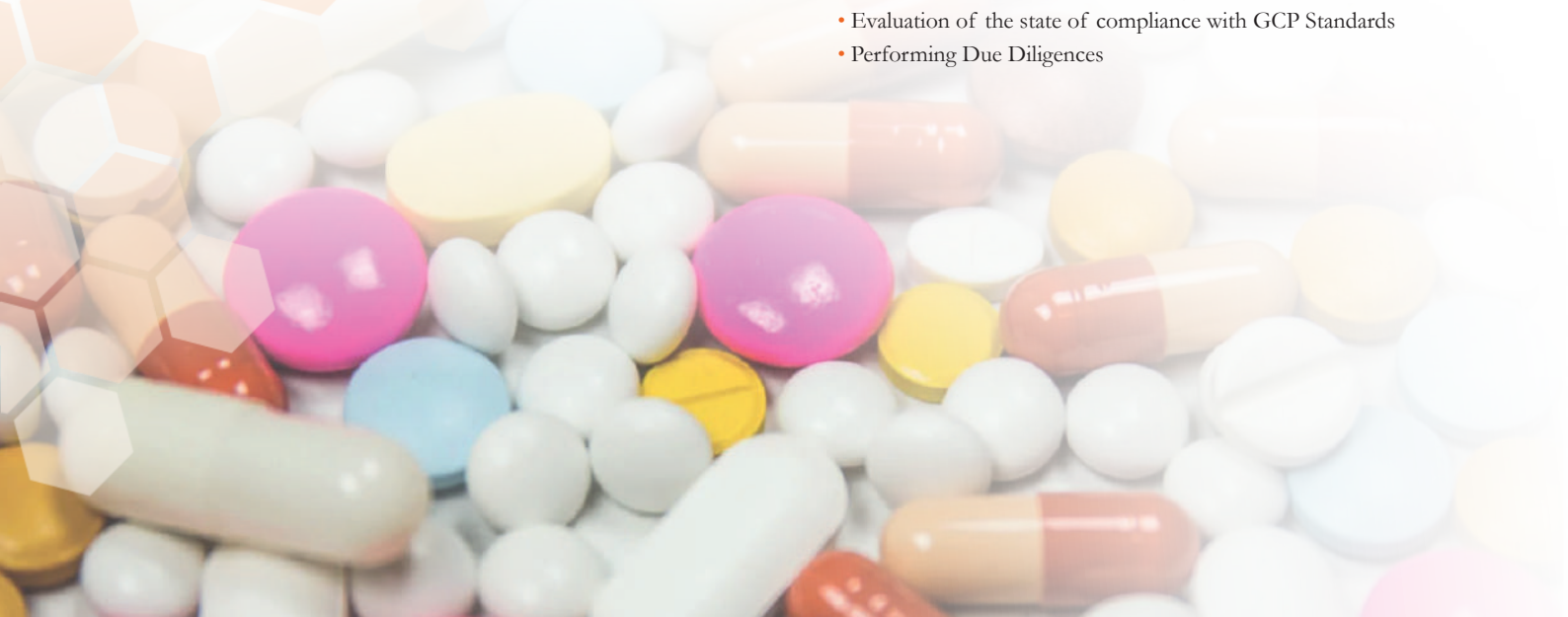
INTERNAL AUDITS AND SELF-INSPECTIONS

Internal audits are the main **self-assessment** tool of the quality system

1. GLOBAL COMPLIANCE AUDITS

Support to Quality Assurance departments

- Evaluation of the state of compliance with GMP Standards
- Evaluation of the operation of the quality system
- Evaluation of the state of compliance with GCP Standards
- Performing Due Diligences



2. SPECIFIC COMPLIANCE AUDITS

Assessment of the current situation

- Audits by Systems (FDA)
  - › Quality System. Material system. Laboratory control system
  - › Production System. Conditioning and Labelling System
  - › System facilities and equipment. Distribution System
- Audits by areas
  - › Warehouses, Manufacturing, Conditioning
  - › Maintenance, Engineering
  - › Quality control, R&D
- Audits for critical elements
  - › Critical Product Quality Attributes (CQAs)
  - › Critical process parameters (CPPs)
- Data Integrity audits
- Qualification and Validation Audits
- Audits of the documentary system in Clinical Trials

3. AUDITS OF ELEMENTS OF THE PHARMACEUTICAL QUALITY SYSTEM

Evaluation of the critical elements of the quality system

- Change control
- Deviation management and CAPA
- Process performance and product quality
- Indicators and management monitoring
- Training and certification of personnel
- Risk management
- OOS and OOT results

EXTERNAL AUDITS

External audits allow us to know **the level of quality and safety** of our suppliers

1. TYPES OF EXTERNAL AUDITS

Evaluation of critical elements

- Audits to API manufacturers
- Audits to excipient manufacturers
- Audits to manufacturers of primary packaging materials
- Audits to manufacturers of secondary packaging materials
- Audits to contract drug manufacturers (CMOs)
- Audits to manufacturers of sterile medicines (terminal sterilization and aseptic process)
- Audits to analytical service providers
- Audits to distributors of raw materials and medicines
- Audits to distributors of veterinary medicines
- Audits to transport agencies of APIs and medicines
- Audits to GxP software developers
- Audits to contract warehouses
- Clinical analysis execution audits (and associated documentation)

2. AUDITS TO MANUFACTURERS OF RAW MATERIALS

Scheme of joint audits and shared costs

Scheduled external audit plans

- Audits programmed by geographical areas
  - › Identify and organize suppliers in the same area
  - › China, India, Europe, etc.
- Audits scheduled by strategic suppliers
  - › Identify laboratories interested in the same supplier
  - › Ability to share audit and report
- Deviation Resolution Tracking

3. CUSTOMIZED EXTERNAL AUDITS

Adaptation to the specific needs of a laboratory

- Audits to a specific supplier
- Audits of a specific raw material
- Audits of a manufacturing process
- Audits to an analytical development
- Audits of a clinical trial

AVAILABLE SUPPORT

PROFESSIONAL FIGURES

- Project Managers experts in Project Management
- Executive consultants with full-time dedication to specific projects
- Multidisciplinary teams:
  - › Experts in Quality System and regulations
  - › Auditors
  - › Engineers
  - › Microbiologists
  - › Experts in the microbiological and physicochemical control laboratory
  - › Experts in galenic development
  - › Experts in the manufacture of sterile medicines
  - › Experts in aseptic processes

ACTIVITIES AND TOOLS

- Drafting and review of technical documentation
- Strategy design
- Execution of investigations
- Statistical analysis
- Education and training for key personnel
- Specialized technical consultancy

ASINFARMA
GESTIÓN DE CALIDAD

ASINFARMA

MICROBIOLOGÍA INDUSTRIAL

"Maintaining quality and microbiological safety throughout the product life cycle is an essential industry requirement"

MICROBIOLOGY APPLIED TO THE QUALITY SYSTEM

Achieving **microbiologically safe** products and raw materials requires highly specialized technical knowledge and **in-depth experience** in the industry itself.

1. GLOBAL COMPLIANCE AUDITS

Regulatory compliance optimization projects

- GAP Assessments and Implementation of new regulations (Annex 1 of the EU GMP)
- Pre-audits for inspection preparation

2. CONTAMINATION CONTROL STRATEGY (CCS)

Custom integral design

- Analysis and evaluation of processes
- Risk identification and risk assessment
- Design of contamination risk mitigation plans
- Drafting of the CCS document

3. MICROBIAL DATA DEVIATIONS (MDD)

Management and investigation of deviations of microbiological results

- Definition of MDD management
- Support in microbiological investigations (Laboratory and complete)
- Definition of CAPA actions

MICROBIOLOGY APPLIED TO THE PRODUCTION DEPARTMENT

Knowing and **controlling** the risks of **microbiological contamination** during the manufacturing process **is vital to guarantee the quality** of our products.

1. FACILITIES

Design, review, optimization and qualification of clean rooms and equipment

- Personnel, material and waste flows
- Cleaning, disinfection and sterilization programs
- Microbiological qualification of controlled environment rooms
- Evaluation and review of the design of isolators and RABS (Restricted Access Barrier System)
- Management and review of isolators and RABS gloves
- Design of strategies and protocols for the qualification of biodecontamination cycles
- Design of strategies and protocols for smoke studies (Smoke Test)

2. PROCESSES

Cleaning, disinfection and sterilization

- Development and validation of equipment cleaning and disinfection processes
- Strategies and protocols to the validation sterilization process (saturated steam, ethylene oxide, dry heat, filtration, ionizing radiation (γ, ß, ..))

3. NON-STERILE PROCESSES

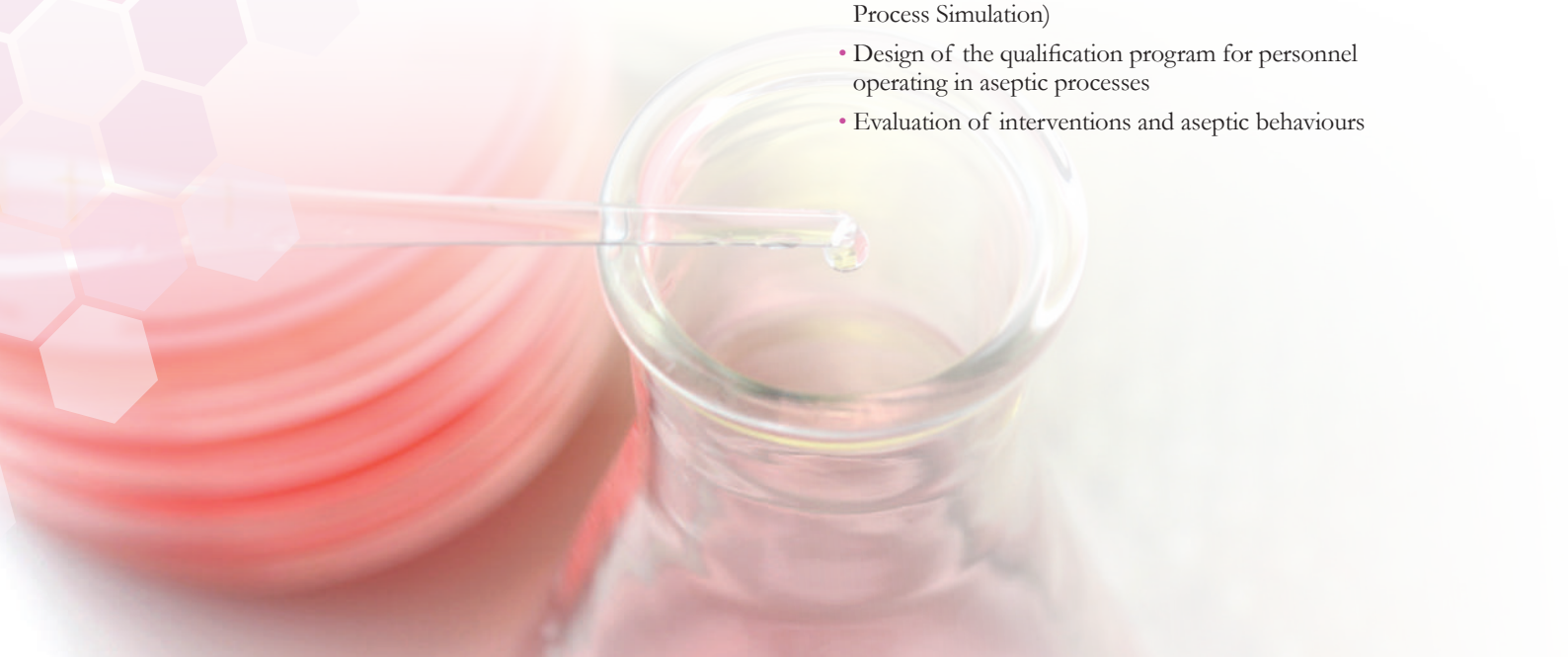
Prevention and control of microbiological contamination

- Risk assessment of microbiological contamination of the process
- Support in microbiological investigations

4. ASEPTIC PROCESSES

Critical elements of aseptic processes

- Risk assessment of the complete aseptic process
- Design of validation strategies for aseptic filling (Aseptic Process Simulation)
- Design of the qualification program for personnel operating in aseptic processes
- Evaluation of interventions and aseptic behaviours



MICROBIOLOGY APPLIED TO THE QUALITY CONTROL LABORATORY

The control laboratory is a **key element in guaranteeing the microbiological quality** of our products.

1. FACILITIES, EQUIPMENT AND PROCESSES

Design, review and optimization of facilities, equipment and processes

- Implementation of Good Microbiology Laboratory Practices
- Design and optimization of the layout of the Microbiology laboratory
- Adaptation and optimization of control processes
- Qualification of equipment in the laboratory (autoclaves, isolators,…)
- Strategies and protocols for the qualification of isolator biodecontamination cycles

2. TESTS AND ASSAY METHODS

Development and definition of validation strategies

- Microbiological methods for non-sterile products
  - › Raw materials and primary packaging material
  - › Bulk product and finished product
- Microbiological methods for sterile products
- Endotoxin determination
- Assessment methods of active principles with biological activity (antibiotics)
- Preservative agents efficacy
- Microbial identification
- In-use stability of multi-dose products (In use stability testing)

3. MONITORING PROGRAMS

Control of contamination by Viable Particles and Total Particles

- Risk analysis for the definition of monitoring points
- Development of the monitoring program
  - › Environment
  - › Surfaces
  - › Isolators
  - › Personnel
  - › Compressed gases
  - › Pharmaceutical quality water

AVAILABLE SUPPORT

PROFESSIONAL FIGURES

- Project Managers experts in Project Management
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  - › Auditors
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  - › Microbiologists
  - › Experts in the microbiological and physicochemical control laboratory
  - › Experts in galenic development
  - › Experts in the manufacture of sterile medicines
  - › Experts in aseptic processes

ACTIVITIES AND TOOLS

- Drafting and review of technical documentation
- Strategy design
- Execution of investigations
- Education and training for key personnel
- Protocol execution
- Specialized technical consultancy

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MICROBIOLOGÍA INDUSTRIAL

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FORMACIÓN ESPECIALIZADA

"Being able to manage new possibilities and expectations is not just a regulatory requirement, it is a real success factor and a matter of business survival"

IN-COMPANY TRAINING

The manufacture of quality, safe and effective products requires **high and updated technical knowledge** throughout the company's organizational structure.

1. DISTINGUISHING FEATURES

Customized for different levels

- Directors and managers
- Supervisors, coordinators and technicians
- Operators and direct labour staff

Flexible modalities

- Face-to-face
- Virtual live
- Tailored to specific needs
- 100% practice applied to real processes

2. CHARACTERISTICS OF THE TRAININGS

Initial and continuing training

- General content of the GMP
- Detailed content by chapter and annex
- Special content on critical issues

Specific training on the job

- Techniques, procedures and operating instructions
- Good work practices, hygiene and safety
- Good documentation and registration practices

Specialized technical training

- Update on regulatory news
- Essential elements of the Quality System and ICH Q10
- ICH Q9 Essentials and Quality Risk Management
- Essential elements of Industrial Microbiology
- Essential elements of ICH Q8, QbD and PAT
- Essential elements of Qualification and Validation

Personalized coaching

- Specific development for key people

QUALIFICATION OF SPECIALIST PERSONNEL

Specialized technical training reduces errors in processes, contributes to the **professional growth** of staff and ultimately to the **success** of the company.

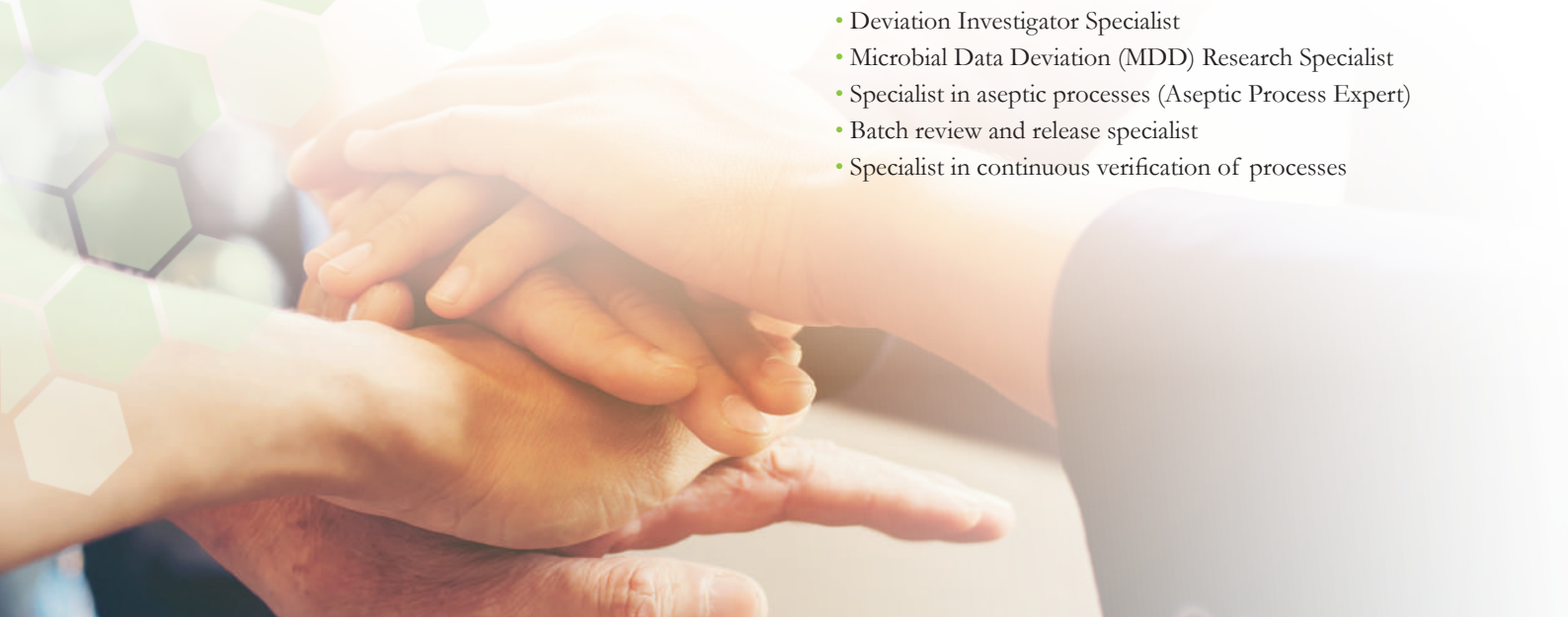
1. ORIENTED TO SPECIFIC PRACTICAL NEEDS

Technical characteristics

- Standard and custom mode (built for you)
- Permanently updated content
- Duration from 15 to 45 hours
- Face-to-face and virtual modules
  - › Theory and practical activities
  - › Individual evaluation by module and final work

Specialist qualification by topic

- Audit specialist
- Deviation Investigator Specialist
- Microbial Data Deviation (MDD) Research Specialist
- Specialist in aseptic processes (Aseptic Process Expert)
- Batch review and release specialist
- Specialist in continuous verification of processes



2. TRAINING IN LEADERSHIP, MOTIVATION AND COMPETENCES

Leadership strategies and expansion of skills

- Oriented to directors and managers
- Aimed at supervisors, coordinators and technicians
- Skills development for key people

Interactive group activities

- Team building
- Awareness in values
- Of expansion of competences
- Teamwork techniques
- Conflict management techniques

Staff motivation activities

- Direct labour personnel
- Supervisors, coordinators
- Technicians and managers

OPEN TRAINING FOR THE WHOLE INDUSTRY

*Performed uninterruptedly since **2009***

Our **annual program** is already a **benchmark in Spain and Latin America**, and a standard of quality and effectiveness for all technicians in the pharmaceutical industry.

1. ANNUAL PROGRAM OF SPECIALIZED TRAINING SEMINARS

Specialized update 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 success factor and a matter of business survival.

All the news in national and international pharmaceutical legislation

- Face-to-face modality (Barcelona and Madrid)
- Live virtual mode
- Between 15 and 25 seminars each year
- More than **270** seminars held
- More than **200** expert teachers
- More than **3,000** participants

Permanent technical update on regulatory requirements and quality systems

2. SOME OF THE MAIN THEMES DEVELOPED

Master programs on critical issues

- Manufacture of sterile medicines
- Pharmaceutical quality system
- Process validation and cleaning strategies
- Maintenance and pharmaceutical engineering
- Regulatory flexibility and reduction of the type of variation
- Risk management applied to each of the industrial activities

Work breakfasts

- Simplify procedure writing
- Key elements of technology transfer
- Practical application of Quality Risk Management
- Cross Contamination Exposure Limits (NOAEL-PDE-ADE)

Independent specialization courses

- Contamination Control Strategies
- Data integrity and data security
- Human error, deviation investigation and CAPA
- Effectiveness and efficiency of the pharmaceutical quality system
- GMP and maintenance. GMP and Lean Management
- Design and validation of spreadsheets
- Visible Particle Inspection
- Cleaning and disinfection of facilities and equipment

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TOPICS RELATED TO VALIDATIONS

1. Preparation of the Validation Master Plan (VMP)
2. Qualification of facilities, services and production equipment
3. Qualification of clean areas according to the new annex I of the GMP
4. Process validation
5. Cleaning validation
6. Validation of aseptic processes
7. Validation of analytical methods
8. AQbD: Analytical Quality by Design
9. Validation of analytical instruments
10. Validation of computerized systems
11. Design and validation of spreadsheets
12. Aseptic Process Simulation tests – (APS, Media Fill)
13. Design, qualification and monitoring of pharmaceutical water systems

ISSUES RELATED TO MULTI-PRODUCT PLANTS

14. Systems and procedures to avoid cross contamination
15. Toxicological limits in pharmaceutical plants Multiproduct

ISSUES RELATED TO GMP

16. Good Manufacturing Practices (GMP) and GMP Standards (PIC/S-FDA-EMA)
17. Manufacture of sterile medicines (PIC/S-EMA)
18. Manufacture of sterile medicines (Annex I of the EU GMP)
19. Preparation of the Pharmaceutical Quality Manual
20. Preparation of the Site Master File required by OMS-PIC/S-FDA-EMA
21. Good distribution and supply practices. Supply chain control
22. GMP in the manufacture of advanced therapy medicines
23. GMP Annex II: Biological drugs. Advanced level
24. Part II of the GMP: Manufacture of Active substances. Advanced level
25. Serialization in the pharmaceutical industry
26. Implementation of a control program for elemental impurities. ICH Q3D
27. Course about the new features in the GMP
28. Risk management for pharmaceutical excipients
29. Quality of biotechnology products
30. Development and manufacture of active substances
31. Good Agricultural Practices and Collection of medicinal plants for active ingredients

TOPICS RELATED TO GLP

32. Preparation for the certification of Good Laboratory Practices (GLP)
33. Good Laboratory Practices for quality control
34. Optimize the management of the quality control laboratory. Updated with new EDQM standards
35. Effective management of out-of-specification (OOS) results
36. Effective management of microbiological data deviations (MDD)
37. Drug stability tests
38. GLP laboratory work procedures
39. Raw Data Integrity in the GLP laboratory
40. Statistical treatment of stability data
41. Qualification of analytical instrumentscos

ISSUES RELATED TO AUDITS

42. How to perform an internal audit (GMP auditor approach)
43. How to receive an internal audit (audited GMP approach)
44. How to carry out an external audit of suppliers (GMP auditor approach)
45. Approval and validation of suppliers of active ingredients
46. Approval and validation of suppliers of medicinal plants
47. How to receive a pharmaceutical inspection (audited GMP approach)
48. How to receive an external client audit (audited GMP approach)

ISSUES RELATED TO STRATEGIC MANAGEMENT

49. Regulatory flexibility and GMP of the 21st century
50. Quality risk management
    (Quality Risk Management - ICH Q9)
51. Pharmaceutical Development
    (Pharmaceutical Development - ICH Q8)
52. Pharmaceutical Quality System (ICH Q10)
53. Productivity and industrial organization by processes
54. Practical risk management course: Risk Ranking and Filtering. Designed with your needs!
55. Practical risk management course: FMEAC
56. Risk Management Workshop: HACCPS

ISSUES RELATED TO THE QUALITY SYSTEM

57. Quality assurance as a productivity tool
58. Investigation of deviations, CAPAs and change controls. Comprehensive vision
59. OOS Investigation
60. Investigation and reduction of human errors
61. Investigation of Data Integrity deviations
62. Tools for root cause analysis
63. System of Corrective Actions and Preventive Actions (CAPA)
64. Product Lifecycle Management. Change Control according to ICH Q12
65. Annual Product Quality Review (APQR/PQR)
66. Periodic management review of the quality system
67. Simplified writing of operating procedures (SOPs)
68. The Data Governance System. Data Integrity. Managerial and technical level
69. Statistical methods for process monitoring

ISSUES RELATED TO CLINICAL TRIALS AND PHARMACOVIGILANCE

70. Good Clinical Practices in the European Union
71. Bioequivalence clinical trials
72. Manufacture of investigational drugs

TOPICS RELATED TO PACKAGING MATERIALS

73. GMP in the manufacture of primary packaging material. ISO 15378.
74. Ecodesign

SPECIFIC GMP MODULES FOR OPERATORS AND ANALYST

75. Finished Product Storage Areas
76. GMP in the manufacture of sterile medicines
77. GMP in packaging
78. GMP in packaging with FDA approach
79. GMP Quality Control laboratory analysts
80. Sterile area. Aseptic practices
81. GMP in the manufacture of oral medicines
82. GMP in engineering and maintenance operations
83. GMP Annex II: Biological Medicines
84. GMP Part II: Manufacture of Active Substances
85. Basic Data Integrity for Operators and Analysts
86. Raw Materials storage areas

ISSUES RELATED TO BIOSECURITY

87. Biohazard analysis in industrial facilities
88. Implementation of a Biosafety plan in biological medicine facilities
89. Practices in classified biosafety areas

TOPICS RELATED TO GDP

90. Implementation of Good Distribution Practices
91. Validation of transport routes

ISSUES RELATED TO LEAN MANAGEMENT

92. Implementation of Lean Management
93. Implementation of Lean Management tools

ISSUES RELATED TO INDUSTRIAL MICROBIOLOGY

94. Implementation and documentation of the Contamination Control Strategy (CCS)
95. Design of environmental monitoring programs
96. Cleaning, disinfection, sterilization and biodecontamination processes
97. Industrial Microbiology
98. Microbiology for non-sterile industrial processes
99. Isolator technology for contamination control
100. Aseptic Process Simulation (APS): Strategies and Validation
101. Monitoring processes and systems for viable particles
102. Environmental monitoring programs (ISO 17141)
103. Microbiology in the quality control laboratory
104. Effective management of microbiological data deviations (MDD)
105. Pharmaceutical water systems
106. Validation of microbiological methods

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