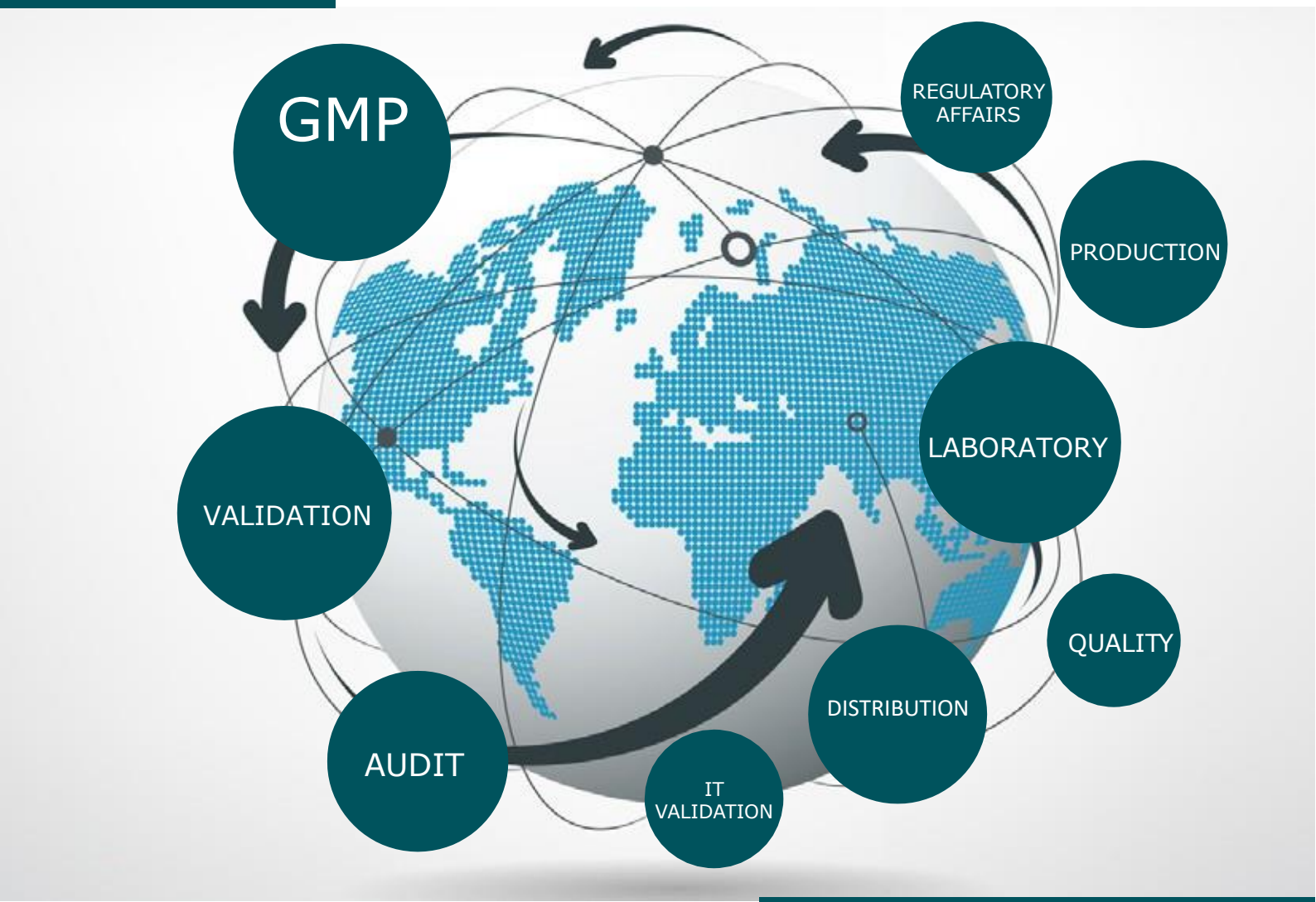
Sisthema



Training Program 2020

On-Site Training

OVERVIEW

Nowadays Training is a fundamental pillar for Pharmaceutical and Medical Device Companies' Business Development.

Sisthema, an ISO 9001:2015 certified company, offers a Training Catalogue that provides practical work tools and regulatory updates, two strong items during regulatory inspections and relevant topics for companies' mandatory and periodic training.

Sisthema is able to:

- create customized technical solutions with a **strong focus on details.**
- design flexible targeted technical solutions, to create value for the customer's company
- analyze customer's needs and build up courses able to satisfy **different targets** (upper management, board, technicians, operators, etc.)
- give assessment tools for the effectiveness of training courses
- develop business improvement plans with customers, thanks to post-course feedbacks

Sisthema has a team of Senior Trainers and Consultants able to design and customize Training programs in the following areas:

- **GMP**
- **Validation and Audit**
- **Quality and Production**
- **Regulatory**
- **Laboratory**
- **Distribution**
- **IT Validation**

Sisthema's Trainers are Senior level Consultants / Trainers with at least 25 years of experience in Pharmaceutical and Medical Device areas.

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English Training and Online Training

Due to the request to organize training courses abroad, starting right now Sisthema offers a selection of our Training Catalogue 2020 in English language also.
All our trainers boast a multiyear experience in Italian and International Pharmaceutical, APIs, Medical Device and Cosmetic companies.

From April 2020 Sisthema organizes Live Online Training using Webinar (both in Italy and abroad) in order to offer our Clients an additional Training service.

So, the Customer can choose two training methods:

- **Classic: a classic training session at customer's site**
- **Webinar: distance training session that includes audio and visual communication between a trainer and attendees**

Sisthema's Training Courses can be totally customized taking into account of the client's working day schedule and the training session's target audience.
Online trainings through Webinar make real the people connection from different places and optimize time and travel costs.

Training Program

GMP: Good Manufacturing Practice

- GMP basic:
  . Staff and training
  . Hygiene and behavior
  . Production requirements
  . Good Documentation Practices
  . Risk Management
  . Qualification and Validation
- Relations with customers and authorities
- Quality Management System:
  . Change Control
  . Deviations
  . CAPA, Corrective & Preventive Actions
  . OOS, Out of Specification
  . Cleaning Validation
  . Audits, inspections and self-inspections
  . Data Integrity

GDP: Good Distribution Practices

- Good Distribution Practices: requirements and implementation
- Facilities for Good Distribution
- Cold chain
- Stability of pharmaceutical products and storage conditions
- Thermal mapping of transports and warehouses
- Temperature monitoring during transports
- Storage of products and materials
- Shipping of finished products
- Traceability of finished products

CAPA: Corrective & Preventive Action

- ICH Q10 guideline "Pharmaceutical Quality System"
- Corrective and Preventive Actions
- Define a CAPA Management Process
- Implementing an effective corrective and preventive action plan
- How to use the information from the CAPA system for "Continuous Improvement"

Quality Risk Management

- Quality Risk management in a pharma company:
  . QRM role and value
  . ICH Q9 guideline
- Regulatory requirements
- Quality Risk Management tools and types:
  . FMEA / FMECA – FTA – PHA - HAZOP, HACCP
- Quality Risk Management: principles and processes
- Risk assessment methods: identify potential critical quality attributes and critical process parameters
- QRM flow:
  . Risk Assessment
  . Risk Control
  . Risk Review
- How and when to apply the QRM: production; quality; development; regulatory; engineering

Risk Assessment

- Introduction to Risk Analysis
- Regulations: ICH Q9; FDA Guidance
- Risk Assessment activities:
  . Risk estimation
  . Risk control
  . Risk communication
  . Risk review
- Risk analysis techniques
- Data analysis
- Statistical evaluations
- Methodology: FTA, FMEA, FMECA
- How to apply the different risk analysis models
- Risk analysis in process validation

Lead Auditor & Inspections

- Reference standard & guideline
- General aspects
- How to schedule and prepare the audit
- How to conduct the audit
- Self-Inspections in the company
- How to schedule and prepare self-inspections
- How to conduct self-inspections

Training Program

Deviation & OOS/OOT Management

- Deviations:
  . management process
  . classification
  . evaluation and recording
  . scheduled deviations or temporary changes
  . the most common deviations according to GMP
  . QC laboratory: data integrity aspects
- The OOS / OOT:
  . guidelines FDA and MHRA
  . management process
  . regulatory expectations
- Authority and FDA inspection findings
- OOS and deviation management: practical examples

Supplier Qualification

- Introduction: guideline
- Identify and define the requirements
- Qualification approach
- Risk Analysis for supplier qualification
- Quality Agreements Management
- Questionnaire tools and direct audits
- Use tests
- Report Preparation and CAPA Plan Verification
- Report Contents
- Responses evaluation and Corrective Actions
- Post-qualification: periodic monitoring

Cleaning Validation

- How to evaluate and calculate PDE values
- cleaning requirements
- cleaning practical aspects management
- How to solve cleaning analytical aspects
- Dealing with microbiological aspects
- Trends for managing cleaning processes

Equipment and Environmental Qualification

- Requirements for GMP equipment in
- Requirements for ISO equipment qualification
- GMP practices for proper instruments qualification management
- Laboratory instruments calibration procedures

Data Integrity

- Practical Analysis of recorded deviations
- Data Integrity System design and implementation
- Quality, IT and regulations for Data Integrity harmonization
- Standard Operating Procedures (SOP) for Data Integrity
- Promote Data Integrity culture and related training
- Data Integrity maintenance

Regulatory & Production Compliance

- Site Master File
- AIFA templates
- Registration File
- Regulatory Agencies Audit
- Essential and non-essential changes
- Revamping in GMP areas
- Regulatory for excipients production for pharmaceutical use
- Examples: documentary requests from government agencies
- Deviation management: roles and responsibilities of QA and Regulatory
- Regulatory communications for recall

Contact Us! 

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