INFOMATICS

UNDERSTANDING GOOD MANUFACTURING PRACTICES

GMP

Infomatics Consultancy

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WHAT IS GMP?

Good Manufacturing Practices (GMP) is a system to standardize the quality of products. Thesepractices conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. The guidelines benchmark theminimum requirements a pharmaceutical or food product manufacturer must meet to assure that their products are of high quality and risk-free to the consumer or public.

GMP in India:

World Health Organization **GMP** guidelines, instituted in 1975, assists regulatory authorities, in different countries, to ensure consistency in quality, safety and efficacy standards, while importing and exporting drugs and related products. India is one of the signatories to the certification scheme. The WHO-GMP certification, which possesses a two-year validity, may be granted, both by CDSCO and state regulatory authorities, after a thorough inspection of the manufacturing premises.

Objectives of GMP:

The objective of **GMP**s is to minimize risks with reference to the manufacturing, packaging, testing, labelling, distributing and importing of drugs, cosmetics, medical devices, blood and blood products, food items etc. These protocols are largely concerned with parameters of quality, safety, efficacy and potency.

EIGHT HYGIENE PRINCIPLES

1. Training of personnel
2. Product Information & Consumer, awareness
3. Transportation
4. Personal hygiene
5. Maintainance & Sanitation
6. Control of Operation
7. Design & Facilities
8. Primary Productions

Advantages of GMP

IMPLEMENTATION OF THE GMP PROGRAM PROVIDES THE FOLLOWING BENEFITS TO YOUR ORGANIZATION:

- Reduces operating costs, as rework and penalties, due to non-compliance,are minimized/eliminated.
- Enhances operating efficiencies with improved quality standards.
- Develops sustainable respect amongst customers, employees, stockholders, regulators and competitors towards your organization,for a demonstrable commitment to GMP.
- Validates conformity to a Management System in line with the new legal requirements .
- Provides leverage to access European and Global Markets.
- Standardized Quality improves product consistency and acceptance in the market.
- Risk-free status enhances reliability of product and trust in your organization.
- Inspire consumers' confidence.
- Increases competitive market appeal.

WE PARTNER WITH YOUR ORGANIZATION TO IMPLEMENT GMP

The highly experienced quality management professionals at **Infomatics Consultancy** help you to design and implement **Good Manufacturing Practices** within the framework of your business. **Infomatics Consultancy** offers comprehensive services that assist you to achieve the goals of quality products, with a risk-free status, through **GMP** implementation. We handhold your organization through the process of implementing **GMP** by:

- Conducting an initial gap analysis.
- Helping you establish policies and objectives.
- Identifing documentation requirements.
- Coordinating document preparation, reviews, approvals, and issuance.
- Managing implementation schedules, training, follow-up actions.
- Aiding your selection of a Registrar with experience in your industry.
- Achieving successful accreditation.

Focus areas of Good Manufacturing Practices.

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GMP PROVIDES GUIDANCE IN BROADLY 5 AREAS OF YOUR BUSINESS:

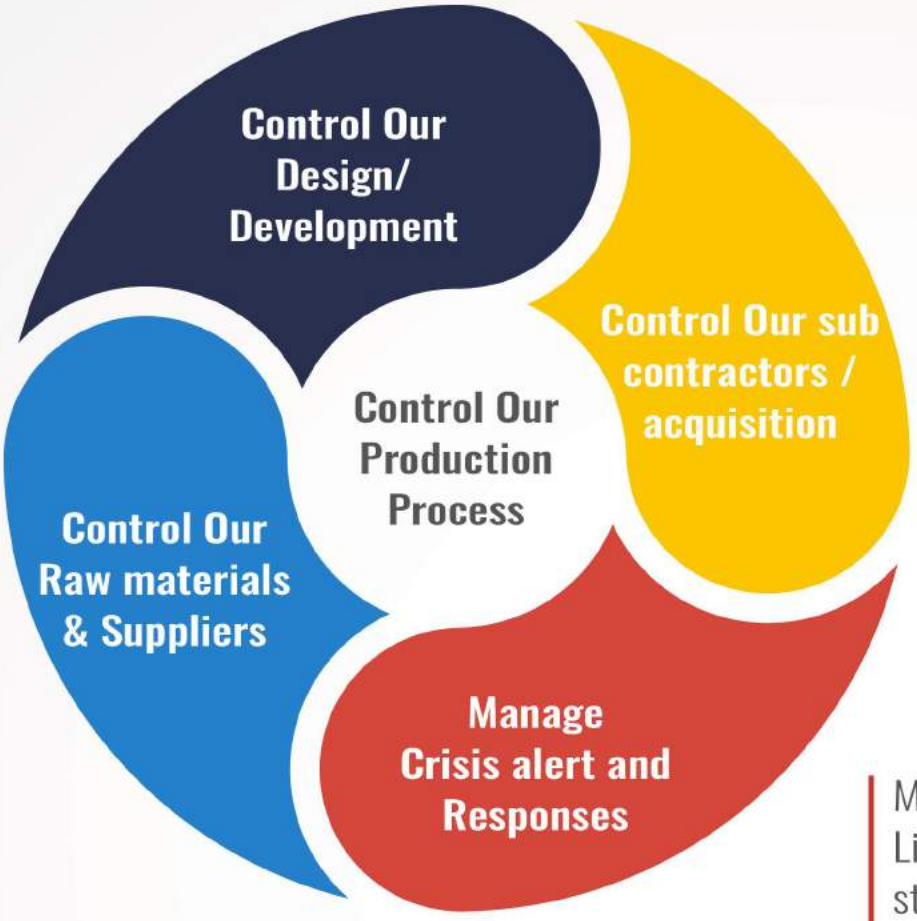
- Personnel
- Premises and equipment
- Production
- Quality control
- Quality systems

GMP CHECKLIST:

- Floors Clean
- Lids on bins
- No cockroaches
- FIFO

Ten Golden Rules of GMP

FDA Good Manufacturing Practice (GMP) Process



Steps to Establishing an Effective GMP

- Committed focus on **GMP** by the Top Management, for a top-down approach.
- Define responsibilities for **GMP** awareness trainings and monitoring of Hygiene and Health.
- Monitor the upkeep of the Premises, Lighting, Ventilation andSanitation, with stringent checks on daily cleaning and the regular maintenance and calibrations of equipment's.
- Only use Approved Suppliers for the procurement of Raw Material andpackaging Material.
- Implement a proper Storage System with systematic Identification and Labelling of Raw Material.
- Apply strict control measures at each stage of manufacturing and packaging operations, to produce a finished product of good quality.
- Storage, shipment and returns should be managed with a view to sustain the quality of finished products.
- Optimize the output of the Quality Control laboratory to confirm that productscomplywith acceptance criteria.
- Quality Processes for monitoring, measurement, corrective action & prevention.
- Establish internal audit program and training,for conducting an initial audit toevaluate conformity to **GMP** requirements.
- Final Certification Audit.

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With a team of highly qualified consultants and trainers, having vast experience across multiple industries, we partner with organizations across the world, to implement and achievehigh standards in **Good Manufacturing Practices**.

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Contact us at **info@iso-consultants** to get your organization **Good Manufacturing Practices** Accredited.