

GMP..... A Journey of 1000 miles starts with 1st Step.....Induction.”

1

- **Mr. R.M. Gupta (M. Pharm.)**, is a free lance consultant for US DMF, COS, ANDA, ACTD, CTD, eCTD and other regulatory submissions.
guptarmg1952@gmail.com
- **He is associated with Perfect Pharmaceutical Consultants Pvt. Limited (<http://sites.google.com/site/ppcdmf>) and Global Institute of Regulatory affairs (Pune, India)**. He is dedicated solely to regulatory profession.
- He is well recognized GMP auditor for Gelatin and hard Gelatin manufacturing Facilities.
- This presentation is solely designed to guide, educate and train regulatory community at large.
- This presentation is based on self experience of the author

What is the pathway for success in GMP?

2

- Establish Goals
- Ensure Proper Organizational Structure
- Ensure Good Man and Material flow
- Match staffing to workload
- Ensure Good SOPs
- Ensure Correct Prioritization of Work
- Establish Accountability
- Create useful Metrics
- Link Rewards to Performance

What is the pathway for success in GMP?

3

- Proper Hygiene and Sanitation at the site
- Validated Machines and equipments.
- Efficient Air and Water Purification Systems
- Expert team of GMP Professionals.
- Quality Materials
- Standard Operating Procedures
- Regular Self Audit
- Regular Training
- Annual Product Reviews

Explain the Legal Doctrine of GMP

4

The GMP Violation is Punishable
Irrespective of its cause.

Culpability under the FD & C
Act does not require

Whether someone

Intended to violate the GMP or

The violation has occurred out of ignorance

- Ref : CDER

What is GMP Credibility ?

5

- GMP Is Being Implemented In More Than 100 Countries for More Than 50 Years .
- More Than Five Thousand Professionals are employed in
- US FDA for GMP Monitoring
- GMP is the highly valued and respected regulation for
- Pharmaceutical Manufacturing
- GMP commands highest number of webinars, tutorials, articles presentation ,online courses and blogs on the internet.
- GMP Professionals command the highest number of job
- opportunities in Pharma Industry.

What GMP Ensures ?

6

GMP ensures the followings:

- Perfect Quality
- Higher Productivity
- Business Appreciation
- Freedom From Complaints
- Improved Controls
- Business Economy
- Self / Institutional Pride

What is Negativity to GMP ?

7

GMP Negativity Examples

- It may require more labors
- It will require expensive training
- It will require expensive renovation
- It will require exhaustive maintenance
- It will demand frequent external audits
- It will require recurring expenses

What are GMP Misconnecepts?

8

- GMP doesn't improve the quality of the drugs. Why to waste money on it ?
- GMP can be manipulated. Why to bother it?
- All GMP acts can not be scrutinized . Why to bother it?
- GMP is nuisance. Why not avoid it? Many others do the same.
- GMP is a voluntary affair. Why FDA is so strict about it ?
- GMP seminars are useless. Why shall we attend them ?.
- Documentation is boring . Why shall we waste time on them?
- GMP is simulation of British System. Why shall we support it?

What are Inexpensive GMP Solutions

9

1. Explore best benefits of leasing against buying equipments
2. Explore incentives to GMP Staff against fat payouts.
3. Explore in-house GMP training against expensive external training
4. Explore expensive facility renovation against in expensive maintenance

How to convenience on GMP Compliance ?

10

The management is always conscious on investments. Hence GMP ideas may meet resistance. The following strategy may do wonders :

Discuss Skillfully

If there is a resistance , stop and reassess your ideas. Present the same differently.

Be positive. Revise your plans and solicit co-operation

What are the Potential Benefits of CGMP ?

11

- Recognition as standard company
- Self pride
- Freedom from FDA 483 Notes
- Freedom from Customer Complaints
- Freedom from devaluation by competitors
- Business Promotions
- Freedom from reprocessing,
- Freedom from rejections and disasters
- Better negotiation on prices

How to Motivate for CGMP Compliance ?

12

- Appreciate New ideas
- Reward Milestone achievement
- Celebrate GMP Certification
- Enjoy Successful FDA audits
- Adopt new Regulations with smile
- Train and get Trained for GMP Compliance

What are the Potential Benefits of GMP?

13

- Possibilities of permanent (repeat) business
- Improvement in quality
- Widespread reputation
- Freedom from FDA actions
- Freedom from system failures.
- Enhancement Of Company Creditability
- Self Inner Satisfaction and Customer satisfaction
- Success In Business.
- 5% of companies who follow real GMP do 80% of turnover in the world

How to induct GMP Compliance ?

14

- Develop Belief in GMP
- Support GMP not only by words but by action also
- Develop commitment and involvement
- Develop harmony and unity in the team
- Build corporate culture that – Supports quality and compliance

How to select staff for GMP Compliance ?

15

- Check his Qualifications (Shall be Well qualified)
- Check his GMP Experience
- Check his track record in GMP compliance
- Check his exposure to GMP
- Check his personality. He shall be Highly energetic and enthusiastic

What is the value of M ?

16

- M (Man) is the most valuable asset of GMP compliance.
- He is more valuable than materials, methods, procedures, machines, facilities, money.
- He shall have integrity, appropriate qualifications, good experience and positive attitude.
- “M” also stands for Machines, Materials and Methods
- All “M” are important

What are the Critical Perquisite for GMP ?

17

- Documentation and Archiving
- Drug Master Files and Dossiers
- Personal hygiene and discipline
- Waste Disposal
- Safety and Efficacy of the product
- Cleaning and sanitation
- Annual Product Review
- Maintenance
- System Validation

What are the General Disbeliefs on GMP?

18

- GMP norms are rigid. They are to be followed exactly as detailed in regulatory Guidelines.
- It is only meant and manageable by MNC
- It does not affect business gains
- GMP makes the simple functions difficult
- GMP demoralizes the workmen as they have to do more work
- GMP precipitates unsolicited problems
- GMP demands unnecessary documentations

How to Energize for GMP Compliance?

19

- Every Management has store of untapped energy. However, the same is not utilized until pro-acted.
- The management must be energized to accept that GMP is universally accepted. It is practiced successfully in 100 countries in the world for the decades together.
- Noncompliers lose energy in worrying about FDA actions and possible closure of the unit
- Compiler gains energy in dreaming about new opportunity for business.

What are the Disbeliefs on GMP?

20

- It is very expensive
- It is very difficult to comply
- It does not ensure business development
- It requires extensive documentation
- It slows down the production
- Its may disclose confidential information
- It doesn't make any difference in quality and productivity
- Its an headache
- We shall do it when asked

How GMP helps Importers?

21

- The importers develop sustainable respect for an organization which demonstrates its proactive commitment to GMP.
- It Decreases the time and cost for importers on third-party testing and product certification
- Importers are more likely contact companies which are GMP Compliant
- It improves the trust and confidence in products and services

What are GMP Basics?

22

1. Plan properly
2. Select People with proven track Record
3. Provide Training
4. Delegate Powers and responsibility
5. Budget Properly
6. Set timelines
7. Induce Persistence
8. Take commitment
9. Set rewards
10. Audit the progress

What are GMP Pitfalls?

23

“Will do later on” ,
“ will do when asked for” ,
“ will do just in time” ,
“will do following a good deal” ,
“cannot do”
“not possible”

What is the Power of GMP?

24

- Can add value to your products
- Can prevent batch failures
- Can improve quality
- Can qualify for tender business
- Can provide professional satisfaction
- Can improve productivity
- Can save 483 Notifications
- Can improve accountability of materials
- Can boost demand and sale

Does GMP is FRIEND?

25

1. F –Friendly environment is built, Faster Working
2. R –Relation with FDA are improved
3. I - Intimacy to quality is achieved
4. E –Errors are prevented
5. N–Nearness to success
6. D –Deviations and changes are prevented removed.
7. S –SOP,s are built, Smooth functions

How GMP fights with errors?

26

1. It facilitate preventive and corrective actions
2. It ensures investigation of Out of Specification issues
It helps in designing SOPs for Zero Error
3. It provides traceability to system failures
4. It enforces validation of machines and equipment to explore inherent defects in design and functionality

What are the benefits of GMP ?

27

- Ensures Quality Recognition and self pride
- Ensures Freedom from FDA 483 Notes
- Promotes the business
- Ensures Freedom from reprocessing, rejections and disasters
- Inducts Better Price Negotiations with the Customer
- Facilitates management of business processes.
The management knows what they have and where to find it.

What are the benefits of GMP ?

28

- Increased efficiency
- Greater quality awareness
- Positive cultural change
- Enhanced communications
- Better documentation
- Economization
- Quick perception of things which are going wrong, and where
- Continuous Improvement in Quality

How to sustain high cost for GMP Compliance ?

29

1. Explore benefits of leasing against buying equipment
2. Explore incentives against fat payouts.
3. Explore in-house training against expensive external training
4. Explore expensive facility renovation against in expensive maintenance
5. Explore Business Collaborations against self overloading

What GMP ensures?

30

1. Consistency and uniformity in production
2. Clarity on what , when, where, why and how about the things to be done
3. Reinventing or duplicating effort are avoided
4. Improvement in management control
5. Reduction in day today problems with failures in product quality

How GMP Promotes your business?

31

GMP

1. GMP boost export opportunities for your products
2. GMP boosts Institutional sales of your products
3. GMP qualifies you for Marketing authorization
4. GMP qualifies for participating in international tenders.

What GMP ensures?

32

- It helps in early maturity of the quality culture
- It permits Continuous measurement of Quality.
- It controls Defect rates .The defects are caught earlier and are corrected at a lower cost.
- It Improved product reliability
- It ensures Better process control and flow
- IT promotes Better documentation of processes
- It creates quality awareness to employees.
- It Reduces in product scrap, reworks and rejections

Final Note

33

- In long run the poor quality system does not save money. The cost of wastages, rework, recall, consumer compensation and loss of good will outweigh accumulated profits
- It is more expensive addressing errors after they have been made than preventing in the first place.
- Implementation of GMP is an investment and not the luxury.
- It is good to design the system to ensure that mistakes do not occur.

Rajkumar Gupta : Thanks you

34

