PHARMSOL NEWS

EUGMP QUALIFICATION: A WAY FORWARD TOWARDS BECOMING A GLOBAL PLAYER

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Why get EUGMP certified?

Regulators from EU are one of the most stringent authorities and getting the facility certified from any EU regulators will not only help you enter the EU market directly but also help you extend your footprints to emerging nations without the need of facing country wise inspections from emerging markets in most of the instances. This saves significant amount of time as well as money. All the EU countries are member of PIC/s consortium hence after the completion of EUGMP Qualification of your finished formulation manufacturing facility, one by default gains the PIC/s qualification status as well.

In addition, post Brexit, such a certification would be helpful to safeguard EU business.

How do you get EUGMP Qualified?

There are two ways to EUGMP Qualify your finished formulations manufacturing facility;

Expedite approval route: EUGMP Certification without submission of dossier

In this particular case, aspirant will not need to file a dossier to trigger inspection. Hence, facility certification could be completed within 6-9 months' time depending on the readiness of the facility. However, one still needs to file a dossier in case one desires a product approval or grant of Marketing Authorisation (MA) to market the product in EU. In short, this is product independent inspection. The advantage here is, whether or not one exports the products to EU nations upon successful certification, one can still retain the EUGMP certification tag during the renewal process of EUGMP certification.

Regular approval route: EUGMP Certification upon submission of dossier

In this particular case, aspirant will have to file a dossier to trigger an inspection. Hence, one needs to first develop the product as per EU requirements and then compile the dossier and subsequent to which dossier needs to be submitted to EU regulator/s. Upon submission of dossier an inspection is triggered automatically. This entire process may take about 2 to 2.5 years' time to get the facility EUGMP certified.

How long is EUGMP Certification valid?

EUGMP certification is valid for three years and is renewable.

What are the major advantages of EUGMP certification?

- There are several advantages of availing EUGMP Qualification status;
- Hallmark for quality standards of the manufacturing facility
- Direct access to EU
- EUGMP certification offers PIC/s qualification status automatically
- Enhanced pricing power for finished product specifically for emerging nations
- Builds confidence in systems which is vital customer's point of view
- Avoids multiple inspections from most of the individual emerging nations
- Visibility on global platform

What is the cost involved in EUGMP certification?

The inspection fee varies from authority to authority from EU member state and the same is specifically stated on individual regulatory authority websites.

Not sure where to begin?

No worries! Hire a professionally managed consultant like PharmSol Group to guide you through the entire process of EUGMP Qualification. PharmSol has decade long experience in assisting companies for their compliance needs including facility certifications from different regulatory authorities.
With its rich experience in compliance, PharmSol has fulfilled dreams of many clients from Asia of pursuing their EUGMP Qualification dream.

PharmSol offers comprehensive EUGMP certification support which encompasses:

- End to End Support – From GAP Assessment to Inspection CAPA Closure
- Full compliance support / upgradation of Quality Management System (QMS) in Dual Language (Chinese – English, if needed)
- Certification in 6-9 months' time from the date of Inspection Application (depending on readiness of the facility)
- Well guided, hand-held support by Subject Matter Experts (SME) to close the observations
- Deputation of APIC/CEFIC/IRCA/ASQ CQA Certified auditor onsite at the client facility even during authority inspection and help for CAPA closure.
- Conducting audits in accordance with ICH Q7, EudraLex Volume 4 and PIC/(s) guidance.

CPhI worldwide
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