

## **Quality Assurance Manager – Somerset, New Jersey, USA**

**Location:** Somerset, New Jersey  
**Salary:** Competitive base salary + bonus  
**Hours:** Full Time  
**Contract:** Salaried, Permanent

### **Our Company**

BAP Pharma are the fastest-growing, independently owned pharmaceutical clinical trials supply organisation, with specialist divisions in Comparator Sourcing, Secondary Packaging & Labelling and Global Storage & Distribution.

Our story is one of incredible growth and success, which has culminated in receiving many prestigious awards, such as recognition in Diversity & Inclusion and Social & Environmental and the expansion of our core operations internationally.

We are now looking for highly qualified, experienced and passionate professionals who are dedicated to providing unparalleled customer service, to continue to drive our business forward and become a part of our success story.

### **Job Description**

The Quality Assurance Manager's role is to ensure that BAP US Inc. is compliant with cGMP, GDP, FDA, EU and ICH regulatory requirements concerning comparator sourcing, secondary packaging & labelling, release, storage and distribution of medicinal products. The Quality Assurance Manager is responsible for safeguarding product users against potential hazards arising from poor distribution practices and be knowledgeable on relevant US legislation.

### **Responsibilities**

The QA Manager will support the Senior Quality Manager in ensuring that a robust quality management system is implemented and maintained, which ensures that:

- Secondary packaging & labeling, testing and release of investigational medicinal products for clinical trials is compliant with relevant guidelines and regulations.
- IMP batch records are reviewed and approved for release.
- Deviations, complaints, change controls and CAPAs are managed, investigated, and performed in a timely manner.
- Shipments and shipping documentation are properly inspected.
- Goods are booked in accurately and in a timely manner.
- The delivered product maintains its quality and integrity during storage and transportation and always remains within legal supply chain. Products are delivered to the right recipients within a satisfactory time.
- Monitoring of Warehouse and Cold Room proper temperature conditions.
- Write, review and/or approve SOPs, and other quality documents as required.
- Support training management system of the personnel
- Assist with regulatory inspections, customer audits and self-inspections
- Responsible for supplier and customer qualification prior to sourcing or supplying.
- Perform on-site audit of suppliers as part of the supplier qualification process where necessary.
- Maintain tracking information for metrics and quality management review.

## Requirements

- Bachelor's degree (or equivalent) in a Science or a related field strongly preferred
- 3-5 years' experience in the pharmaceutical industry, preferably in the field of comparator sourcing and/or clinical packaging and labelling
- Familiarity with EQMS, OrderWise, or similar systems
- Experience hosting/performing internal and external audits is preferred

## Competencies

- Excellent communication skills (both written and verbal) with internal and external partners
- Ability to prioritise effectively, can conform to shifting priorities, demands and timelines through analytical and problem-solving
- Attention to detail and thoroughness
- Results focused
- Ability to multitask
- Ability to work under own initiative and collaboratively as part of a wider team

## Working Conditions

- Reporting directly to the Senior Quality Manager
- BAP is in the process of relocating from Landing to Somerset (NJ). The role will be based permanently in Somerset once the relocation completes at end of 2022/early 2023. Depending on employment start date, the individual may be required to commute to our Landing site until the relocation is completed.

BAP Pharma are committed to enabling a supportive work environment, which is diverse and inclusive and based on mutual respect.

BAP Pharma offers comprehensive training and development programmes to employees to enable them to excel in their roles. We provide our team with a platform in which to continually progress and excel and deliver on our promises to our clients.

**BAP Pharma – Promise delivered. Our people are results driven, tenacious and customer focused. If you think you have what it takes to be part of a successful team with an exciting future, please apply today!**

You can apply to this role through the BAP Careers Portal [here](#).