

# GRIFOLS

Grifols Biologicals

## Auditor, Regulatory Compliance

Grifols has been a leader in the healthcare industry since 1940 by creating innovative products and services based on the values of ethics, quality and responsibility. Grifols' focus and mission is to fulfill the needs of its patients, as well as healthcare professionals working in therapeutics, pharmacy, diagnostics and blood banking. For more than 60 years, Grifols has developed, manufactured and marketed products designed to improve human health. At our Los Angeles facility, Grifols manufactures plasma derived biopharmaceutical products of proven efficacy, quality and safety. The Grifols family of companies includes Grifols Inc., Grifols USA, Grifols Biologicals, Biomat USA and Plasma Collection Center, Inc. For more information, please visit our website: <http://www.grifolsusa.com/>.

**Grifols Biologicals** researches, develops and produces therapeutic proteins from human plasma and uses the most cutting-edge technology for protein purification. Our modern facilities are organized according to Good Manufacturing Practices (GMPs) and have been certified under the FDA Establishment License. This division of our company has an immediate opening for a **Auditor** in our Regulatory Compliance department offering competitive salary, along with an excellent benefits package, including medical, dental, vision, 401(K) plan, life insurance, educational assistance, and five (5) weeks of paid time off.

### **Position Summary:**

- This position will include the following major areas of responsibility. Conduct internal cGMP audits, conduct domestic and international supplier audits, write audit reports, write summary reports including (trends, tables, graphs, slides), participate in the audit response and corrective action process, verify implementation of corrective actions, write and revise documents and procedures. In addition, conduct training on procedures, cGMP, industry standards and practice and technical training as appropriate. Hold and attend meetings. Give presentations, verbal and audio-visual. This position will interface with others inside and outside the company up to the VP level. Will participate in customer audits, third party audits and national or international regulatory agency audits.

### **Job Responsibilities:** (include the following. Other duties may be assigned)

- Coordinate, schedule and participate and/or perform internal cGMP and GLP compliance audits of the manufacturing, quality control testing, and warehouse facilities and operations.
- Coordinate, schedule and participate and /or perform cGMP and GLP compliance audits of company's suppliers and contract laboratories. This may require approximately 10% domestic and international travel.
- Coordinate, schedule and participate in audit activities associated with company's customers.
- Participate and assist in the activities associated with regulatory inspections.
- Play an active role in the development, coordination and presentation of training programs within the areas of responsibility for the department and for others.
- Writes and revises documents and procedures relevant to the auditing function.
- Issues audit reports, assist as required in the audit responses, verify the implementation and evaluate the appropriateness of corrective actions.
- Assist in other departmental activities as determined by the department manager.

**Skills/Qualifications:** (To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions).

- At least four years of experience in Regulatory Compliance, Regulatory affairs, Quality Engineering, Quality Control or Quality Assurance conducting cGMP and GLP audits of Manufacturing, Laboratory and Warehouse operations internal to companies and/or suppliers.
- Experience in the Pharmaceutical, Biologics, Medical Device or other Health Care industry is also required.
- A minimum of a Bachelor Degree in one of the Life Sciences, Health Care or other Science or Engineering Bachelor Degree.
- Certification in industry auditor training programs, such as (ASQ, RAPS, ISO etc.) is mandatory.
- Working knowledge and understanding of concepts of cGMP and GLP.
- Understanding of industry standard operational/manufacturing practices.
- Knowledge of US and international regulations and practices pertaining to the manufacture and testing of pharmaceutical and biologics products.
- Good verbal, written communication and negotiations skills.
- Computer literacy with proficiency in MS Word, Access, and knowledge of Excel and PowerPoint.
- Able to work independently with minimal supervision.
- Well developed communication skills especially in stand-up presentation or facilitation.
- Willing to travel as needed, domestically and internationally, with overnight stays from one to two days to up to two weeks.
- Good leadership and interpersonal skills, with the ability to direct the work of others.
- Able to adhere to Manufacturing and QC Laboratory gowning and safety procedural requirements. This position requires frequent gowning in-order to support audit activities in the environmentally controlled facilities during internal audits, customer audits, regulatory audits and supplier audits.

**\*If interested, please submit your resume to [Kerry.Clark@grifols.com](mailto:Kerry.Clark@grifols.com), with a subject line of Auditor.\***

**Or you can submit your resume online by clicking on (or copying and pasting into your internet browser) the link below:**

[http://hostedjobs.openhire.com/epostings/submit.cfm?fuseaction=app.dspjob&company\\_id=16052&jobid=214419&jobboardid=632](http://hostedjobs.openhire.com/epostings/submit.cfm?fuseaction=app.dspjob&company_id=16052&jobid=214419&jobboardid=632)