

MaSTherCell

The global cell and gene therapy CDMO partner



We are currently looking for a:

QUALITY ASSURANCE MANAGER

Full-time

Webster, TX - USA

Interested to work with us? Send your resume and a cover letter at jobs-us@masthercell.com

Quality Assurance Manager

RESPONSIBILITIES

- With the collaboration of the requesting department, establish the pharmaceutical quality report (PQR) requested by the customers annually.
- Implement an empowerment culture.
- Maintain opened and effective communication with all other departments.
- Provide QA training to other team members.
- In compliance with the Investigational Medicinal Product Dossier (IMPD) and current regulations, review and challenge the Master Batch Record, Specifications and analytical methods.
- In compliance with the IMPD and current regulations, review and challenge the Material Release, Drug Product Label, and Environmental Monitoring.
- In compliance with the IMPD and current regulations, review and challenge the batch records requested by the customers in a timely manner.
- In compliance with the IMPD and current regulations, review and challenge the Deviation, Curative and Preventive Actions (CAPA), Change Control and Risk Analysis related to batch production.
- Update, analyze the process of batch release with key performance indicator (KPI). Propose and realize adapted action.
- Be subject matter expert regarding QA questions related to products.

SKILLS/QUALIFICATIONS

- Rigorous.
- Conscientious.
- Versatile.
- Open-Minded.
- Quality-Minded.
- Good Communication Skills.
- Willing to Bring New Challenges.

EDUCATION/EXPERIENCE

- Bachelor's Degree in Biology or Clinical Chemistry.
- Experience in QA preferred.

- ▶ **APPLY TO: jobs-us@masthercell.com.**
- ▶ **Please be sure to include your salary requirements.**
- ▶ **NO TELEPHONE CALLS PLEASE!**