QUALITY ASSURANCE SPECIALIST

Join a leading company specializing in the manufacture of synthetic hydroxyapatite and play a key role in ensuring the highest standards of quality.

As a Quality Assurance Specialist, you'll ensure the effectiveness of our Quality Management System, contributing to compliance with ISO 9001:2015 and preparation for ISO 13485:2016.

Take this opportunity to join a company that values innovation, trust, and a supportive environment for our talented team!

KEY RESPONSABILITIES:

- Plan and conduct internal audits of the QMS in accordance with the annual audit program;
- Perform regular checks on the factory floor to ensure compliance with procedures and work instructions;
- Monitor and verify the implementation of corrective and preventive actions (CAPA);
- Record, investigate, and follow up on internal non-conformities until closure;
- Support the management and control of QMS documentation (SOPs, WIs, forms, records);
- Verify compliance with traceability requirements in production;
- Support the qualification and evaluation of critical suppliers;
- Monitor external audits (certification, customers) and assist in the preparation of evidence;
- Analyze quality indicators and propose improvement actions;
- Assist in training and raising employee awareness of quality issues;
- Participate in management review by collecting and analyzing QMS data;
- Monitor compliance with calibration, maintenance, and periodic verification deadlines;
- Support the management of customer complaints and root cause analysis;
- Contribute to the preparation and implementation of ISO 13485 requirements;
- Prepare audit and verification reports identifying deviations and opportunities for improvement.

QUALIFICATIONS AND HARD SKILLS:

- Minimum qualifications Bachelor's degree (preferably in Chemistry, Pharmacy, Biochemistry, Biotechnology, or a related field);
- Training in Quality Management Systems (preferably);
- 3 to 5 years of professional experience in Quality Assurance in the pharmaceutical, medical device, cosmetic, chemical, or food industry;
- In-depth knowledge of ISO 9001:2015 and its requirements;
- Knowledge of ISO 13485:2016 (medical device requirements);
- Experience in planning and conducting internal audits;
- Knowledge of root cause analysis methodologies (5 Whys, Ishikawa, 8D);
- Experience in non-conformity management and CAPA;
- Knowledge of document control and record management;

- Familiarity with Good Manufacturing Practices (GMP);
- Knowledge of quality indicators and data analysis;
- Notions of risk management (ISO 14971) would be a plus;
- Proficiency in Office tools (Excel, Word, PowerPoint);
- Strong command of spoken and written English

SOFT SKILLS

- High attention to detail and accuracy;
- Critical and analytical thinking;
- Ability to work independently and manage priorities;
- Assertive communication skills (reporting deviations constructively; questioning practices);
- Ability to influence and raise employee awareness of quality;
- Resilience and ability to deal with resistance to change;
- Good interpersonal skills;
- Focus on continuous improvement.

WHAT WE OFFER

• Integration into a rapidly expanding company and a dynamic and committed team;
• Salary package in line with the role;
• Health insurance and other company benefits.

If you are motivated to embrace this professional challenge, please send your CV, referencing **"Quality Assurance Specialist,"** to the email careers@fluidinova.com.