Services

JLSC is your consultant for project management and interim management. We provide the medical devices and pharmaceutical industry with integrated consulting services and with specific training in the field of approval and quality management tailored to your requirements.

Our Vision

We rely on well-educated, highly motivated and dependable specialists.

We speak your language and we bank on long-term co-operation.

We guarantee joint success and targeted further development.

Our Mission

We work on a top quality, personality and technical expertise basis.

We look beyond the horizon and always advise to the best of our knowledge and belief.

We identify ourselves with your challenges.

We stand by you in a more and more complex regulatory environment. Together, we work out a solution perfectly tailored to your requirements.

Biological Safety Evaluation and Toxicological Risk Assessment (ISO 10993-series)

- Biological Safety Assessment.
- Toxicological Risk Assessments.
- Planning of chemical analyses, in-vivo analyses, and in-vitro analyses.

Sterility Assurance

- Documentation, planning and execution of process validations, for instance, cleaning processes, sterilisation processes using ETO, gamma and saturated vapour.
- Revision and optimisation of reprocessing information in accordance with ISO 17664 for central sterilisation.
- Development and support for microbiological and/or chemical monitoring of the cleaning and sterilisation process, process water and your clean rooms.

Deviations in Quality & Complaint Handling (NC, CAPA, Complaints)

- Investigation, assessment and remedying of client complaints and deviations in quality (NC, CAPA).
- Carrying out investigations of deviations and analysis of the failure root cause.
- Definition of correction and prevention measures according to 21 CFR 820 and ISO 13485.

Medical Device Regulatory Affairs (RA)

- Drawing up and dealing with regulatory approval world-wide of your medical products.
- Execution of technical documents for international registration and approval.
- Preparation of an approval strategy along with planning and implementing it.

Packaging Development

- Development of packaging systems, sterile barrier systems and secondary packaging, taking functionality and usability into consideration.
- Drawing up validation documentation along with planning and supporting the carrying out of transport validations according to international standards and guidelines.
- Execution and optimisation of the technical documentation, such as specifications and drawings.

Verification and Validation (V&V)

- Drawing up validation documentation along with planning and supporting the carrying out of IQ, OQ and PQ of installations.
- Planning and co-ordination of biocompatibility studies along with chemical, physical and mechanical tests.

Product Development (R&D)

- Supporting the development of new products with focus on aspects of reprocessing.
- Planning and co-ordinating biocompatibility studies.
- Regulatory and standard gap analysis and introduction of the RA perspective in development projects.

Supplier Quality Management (SQM)

- Independent planning of your annual audit plan. Timely execution of supplier audits according to EU MDR REGULATION (EU) 2017/745, ISO 13485 and 21 CFR 820 and your in-house specifications.
- Preparation of audit reports and of the concluding management report.
- Processing deviations arising from the audit in collaboration with the affected suppliers and your in-house interfaces.

Contact us for an introduction without obligation.
We are looking forward to hear from you!

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