# JLSC Your Partner for RA, QM, Cleaning, Packaging, Sterilization, Reprocessing, Biocompatibility, and Toxicology

JLSC company presentation - general

# We are JAKSCH LIFESCIENCE CONSULTING


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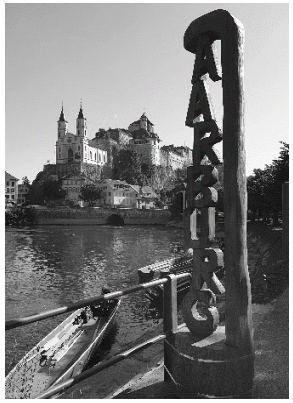

## From The Heart Of Europe
**To The World**

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JAKSCH LIFESCIENCE CONSULTING

# JAKSCH LIFESCIENCE CONSULTING is your ISO 13485-certified consulting firm

- We diligently focus on **your most vital projects** in the fields of **Regulatory Affairs, Quality Management, Cleaning, Packaging, Sterilization, Reprocessing, Biocompatibility, & Toxicology**

- **You** can rely upon our values:
  **Excellence, Entrepreneurship, & Partnership**

- Our mission is to support **You** with our **Professional Team Members** & **Successful Working Method**

JAKSCH LIFESCIENCE CONSULTING

# 3 values characterize the JLSC corporate culture & shape our operations

**Excellence**

Highly qualified employees
Swiss quality
Result oriented

**Entrepreneurship**

Entrepreneur in the company
Willingness to take risks
Flexible and adaptable

**Partnership**

Partnership with clients & teamwork
Adherence to your deadlines
Listening, planning, and executing for you

# JAKSCH LIFESCIENCE CONSULTING Core Competencies

- Biological Safety Evaluations and Toxicological Risk Assessments
- Cleaning, Packaging, Sterility, and Reprocessing Assurance
- Quality Management & Deviation Management
- Regulatory Affairs
- Packaging Development
- Verification and Validation
- Product Development
- Supplier Quality Management

# Biological Safety Evaluation and Toxicological Risk Assessment

- Biological Safety Evaluations
- Toxicological Risk Assessments
- Planning of chemical analyses
- Planning of in-vivo analyses
- Planning of in-vitro analyses
- In-silico modeling

# Cleaning, Packaging, Sterility, and Reprocessing Assurance

- Planning, executing, maintaining, and documenting your process verifications and validations in the areas of cleaning, packaging, sterilization and reprocessing processes
- Revision and optimization of reprocessing information for your customers central sterilization departments
- Development, planning, executing, maintaining of your microbiological or chemical monitoring of the cleaning, packaging, sterilization, process water and clean room processes

# Quality Management & Deviation Management

- Investigation, assessment, and remedying of customer complaints and deviations in quality (NC, CAPA)
- Carrying out investigations of deviations and analysis of the failure root cause and, if needed, human health hazard assessment
- Definition of correction and prevention measures according to the latest applicable legislations and standards
- Ensuring the timely execution of field safety corrective actions
- Solving your needs after receiving inspection and audit findings to avoid further market access issues

# Regulatory Affairs

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

# Packaging Processes and Development

- Development of packaging systems, sterile barrier systems, and secondary packaging, taking functionality, sterilization 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 optimization of the technical documentation, such as correct material selection, packaging specifications, and drawings for technical and regulatory applications
- Defining the labeling and UDI requirements

# Verification and Validation

- Drawing up risk-based verification and validation documentation along with planning and supporting the carrying out of IQ, OQ, and PQ of products, services, and installations for
  - Cleaning equipment and processes
  - Packaging equipment, packaging systems and processes
  - Sterilization processes
  - Reprocessing processes
  - Analytical, biocompatibility, and toxicological procedures
  - Laboratory processes

# Product & Service Development

- Supporting the development of new products and services with a focus on aspects of cleaning, packaging, sterilization, reprocessing, biocompatibility, and toxicology, including risk management and usability obligations
- Selecting the right materials and auxiliary materials
- Planning and coordinating biocompatibility and toxicological studies
- Regulatory and standard gap analysis and introduction of the regulatory perspective in development projects

# Supplier Quality Management

- Independent planning and timely execution of supplier audits according to your annual audit plan
- Preparation of audit reports and of the necessary dashboard reports for your management review
- Processing deviations arising from the audit in collaboration with the affected suppliers and your in-house interfaces

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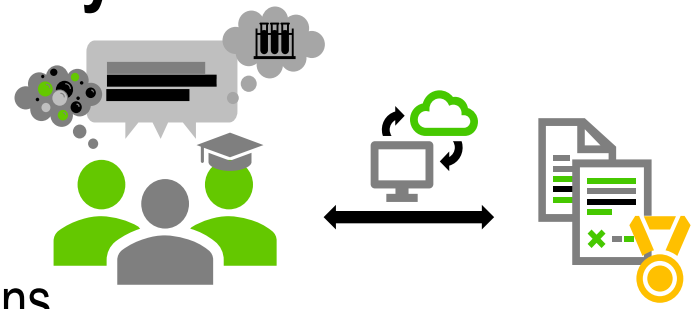
# Catalyzing success:
# → Implementation tailored for you, with you



- Implementation of proven methods
- Achievable, innovative, & comprehensive solutions
- Interactive & interdisciplinary teams with **you** & **JLSC** members
- Support during the regulatory phase
- Knowledge transfer to **your** staff

JAKSCH LIFESCIENCE CONSULTING

# Our holistic services for your product lifecycle

**Product Concept**

**Research & Development**

- Product development support
- Packaging development
- Regulatory & standard gap analyses

**Validation**

- Biological evaluation plan & report
- Toxicological risk assessment
- Process verification & validation

**Manufacture**

- Cleanliness & sterility assurance
- Plan & coordinate biocompatibility studies
- Plan & coordinate testing strategies

**QA / RA**

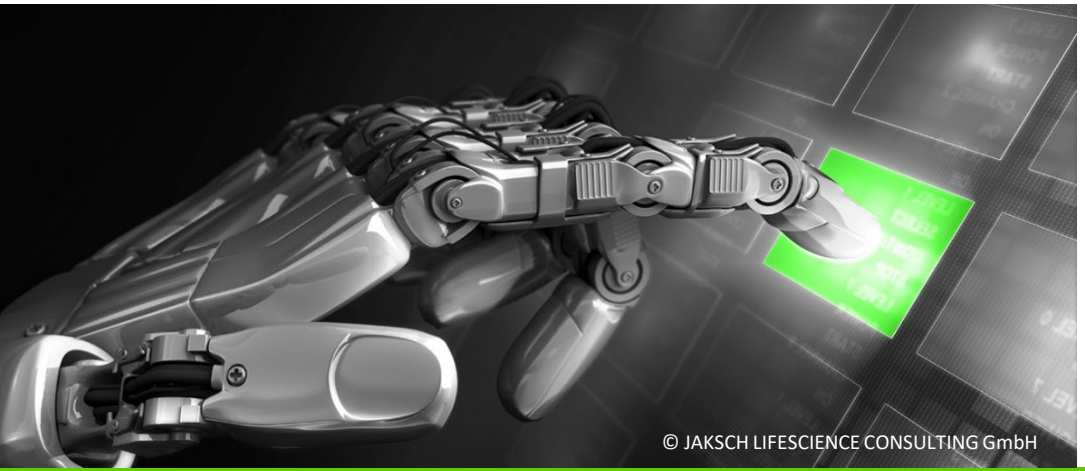
- Regulatory affairs
- Supplier quality management
- NC, CAPA, Complaints

**Post Market**

**We stand by you in a more and more complex regulatory environment**

**Together, we work out a solution perfectly tailored to your requirements**

# Which projects can we support you with?




**Contact us to learn more and start finding solutions today**

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