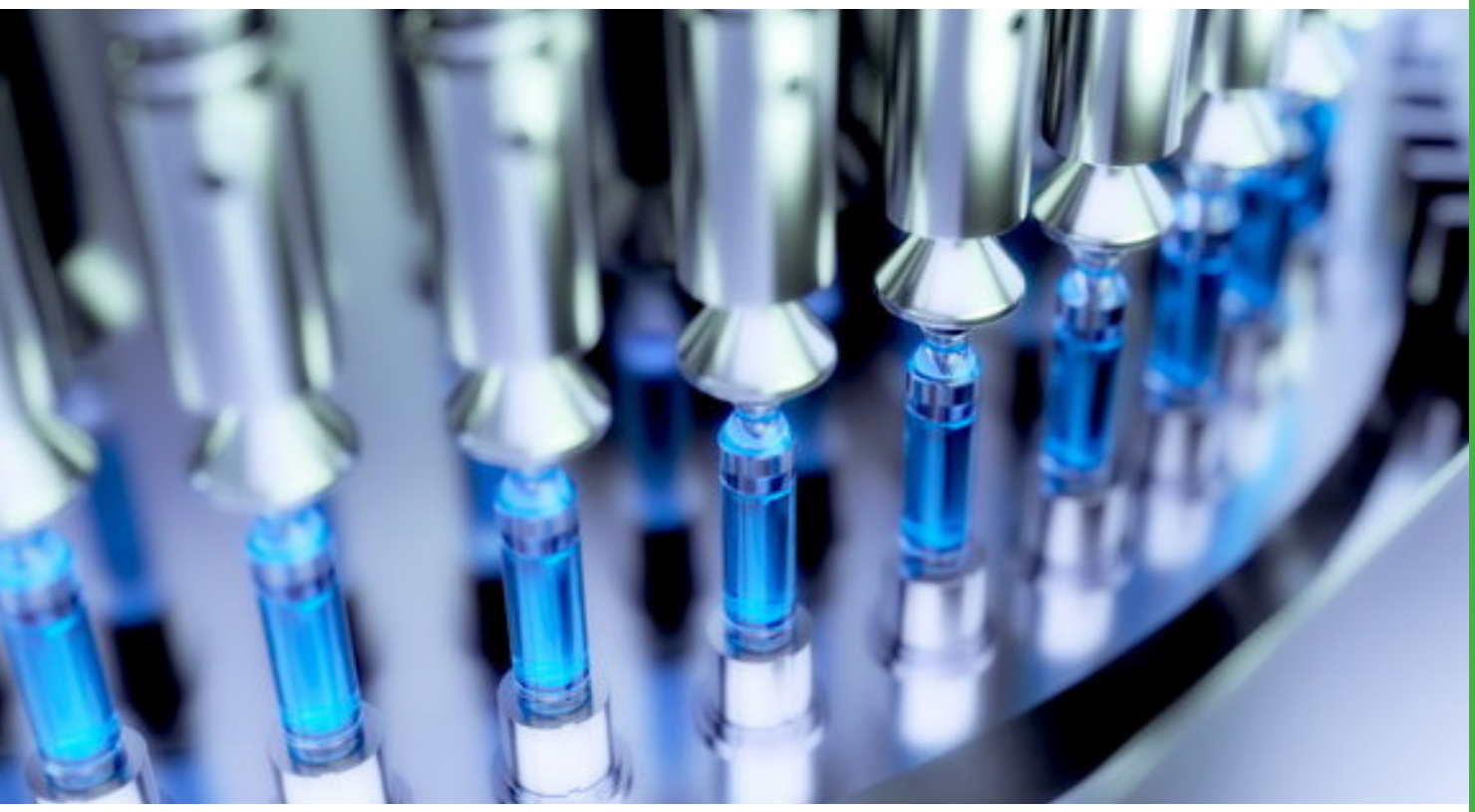
PROMERIDIAN

2023

PROMERIDIAN SOLUTIONS

Business Proposal
Our Pharmaceutical Industry Services Brochure



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OUR WEBSITE
www.promeridian.tech

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1. About ProMeridian Technologies

ProMeridian is a leading pharmaceutical industry consulting and services company driven by a passion for excellence and innovation.

Our experienced professionals offer complete services including turnkey projects, quality management, management and implementation of different types of extensions, process improvement, validation of computerized and cleaning systems, research and development...to help our customers achieve compliance and peak performance

We are committed to providing exceptional service and ensuring customer satisfaction, making us a trusted partner in the pharmaceutical industry.

2. Pharmaceutical Quality Services

ProMeridian offers a range of Pharmaceutical Quality System services designed to help our customers optimize their operations and achieve the highest levels of efficiency and compliance.

With a team of experienced professionals and a commitment to excellence we are a trusted partner for companies looking to improve their Quality systems.

Our services include the design of the Quality strategy, the integration of risk management, internal audits, the implementation of quality management software, support and preparation for various regulatory inspections as well as several other services.

We understand the complexities of the pharmaceutical industry and the importance of ensuring compliance with regulations and standards, and we work closely with our customers to design custom quality systems that meet their specific needs.

Third Party Audits

To comply with regulatory and GMP and/or ISO requirements, ProMeridian offers its customers third party audit services.

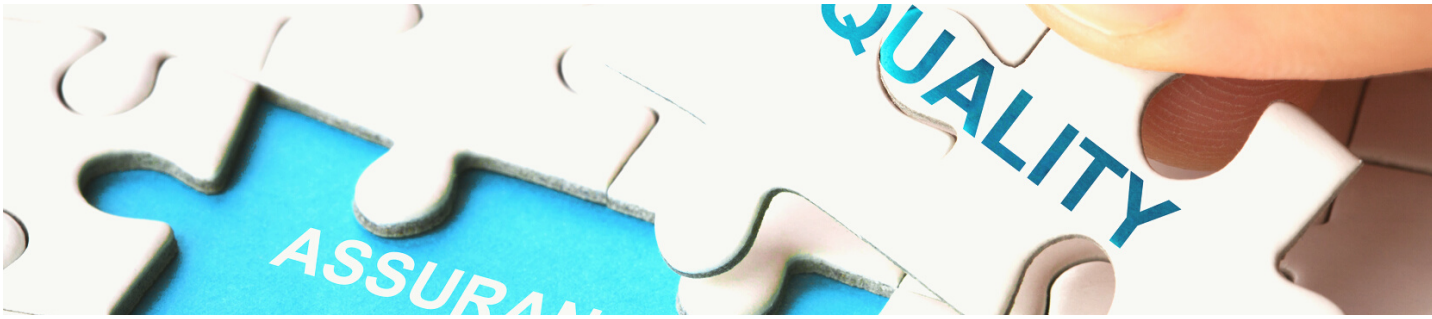
Types of audit:

- Assessment of compliance with various GMP standards: EMA, FDA, SFDA and preparation for approval inspections.
- Evaluation of the conformity of the different Systems: Quality Assurance, Production, Quality Control, Logistics...
- Audits concerning the integrity of the data and the preparation for the validation of the computerized systems.
- Audits concerning the reliability of Validation and Qualification systems.
- Audits to assess and improve process performance, verify the effectiveness and compliance of quality attributes and critical process parameters implemented to increase yields and reduce losses.

Quality Assurance Services

Quality Assurance services provided by Promeridian can be performed in-house by GMP consultants with experience in national and international projects:

- Product Quality Review (PQR)
- Verification of Operational Procedures (SOP)
- Assistance in the development and implementation of the documentation necessary to write the specifications (User Requirement Specifications: URS)
- Process validation
- Cleaning validation
- Computerized Systems Validation
- Support and follow-up to obtain the various ISO certifications: 9001, 14001 and 13485.



Electronic Batch Records

Electronic Batch Records are a digitized form of records; They help reduce errors, streamline traceability and generate a reduced volume of documents.

Current EMA and FDA Good Manufacturing Practices (cGMP) require proof of proper handling at every stage of the production process.
Paper-based systems are cumbersome and error-prone while the Electronic Batch Recording (EBR) system removes this burden for quality and manufacturing teams. It improves product quality and performance indicators.

Promeridian can ensure compliance and improve efficiency by automating your paper systems with an integrated EBR system.

3. Engineering & Projects

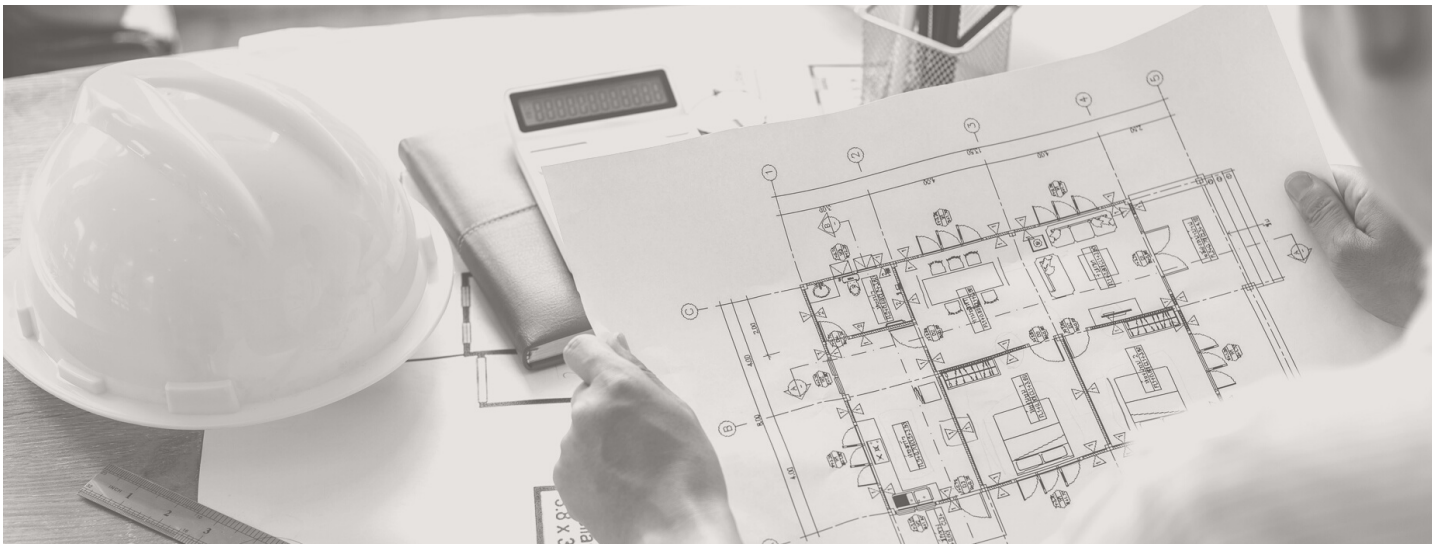
Our engineering and project management services are designed to help your business excel in an ever-changing industry.

With a seasoned team of experts, we merge technical know-how and regulatory expertise to deliver unparalleled solutions that exceed expectations.

At ProMeridian, we understand the value of a holistic approach, which is why we offer complete turnkey projects tailored to your unique needs.

From engineering and logistics to construction, our turnkey solutions ensure seamless integration of your infrastructure, production machinery and systems.

Our commitment to quality, innovation and customer satisfaction sets us apart; contact us today to find out how ProMeridian can transform your business.



Turnkey projects

With a team of proven experts in engineering as well as technical and regulatory requirements of the pharmaceutical industry, ProMeridian is your trusted partner to undertake complex and unique projects and provide quality and timely solutions that meet regulatory requirements.

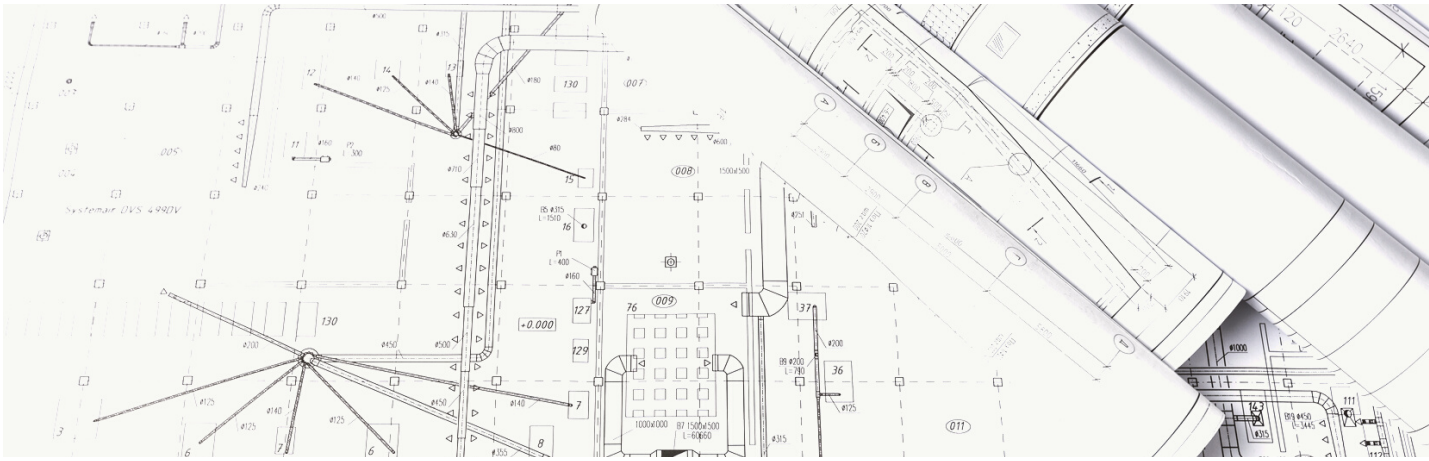
ProMeridian can work in different combinations of responsibilities depending on customer requirements.

ProMeridian, with its team of experts with deep knowledge, can suggest the best equipment, machinery and systems with the right cost and quality.

Design reviews

ProMeridian can help you by providing complete solutions or alternatives if needed regarding your designs. ProMeridian may also offer a second opinion and validation regarding designs made by a third party.

Our subject matter expert engineers will be able to assess design issues and suggest improvements and long term solutions.



Concept design

Conceptual design is the key to developing a fully international GMP compliant design that considers processes, technologies and equipment, adapting them to the available space.

Without proper conceptual design, any subsequent stage of installation may be subject to many changes, which were not thoroughly considered at the outset as possible options.

4. Qualification & Validation

At ProMeridian, we understand the importance of efficient and compliant qualification and validation for the pharmaceutical industry. We offer a full range of services to ensure that your equipment and facilities meet regulatory requirements and perform as intended.

Our Qualification & Validation services are designed to optimize your operations and help you achieve your goals.

Qualification of Equipment and Installations

ProMeridian can help customers decide their qualification strategy, from a traditional approach to an ASTM (American Society for Testing and Materials) approach

In a traditional approach, the qualification of installations and equipment can include the whole process, from the specification of the user's needs and the risk assessment, through the validation master plan, FAT, SAT, DQ , IQ, OQ and PQ

ProMeridian can assist you in particular for your qualification activities of:

- Air treatment systems
- Clean rooms: Architecture, qualification and requalification of environmental conditions.
- Utilities: Purified Water (PW), Water for Injections (WFI), Pure Steam (PS),
- Compressed air and gas (nitrogen, etc.)
- Thermal equipment and installations: Autoclaves, sterilization tunnels, freeze dryers, reactors, freezers, ovens, furnaces, incubators, stores, cold rooms and stability rooms.
- Production equipment

Validation Process

Process validation includes a series of activities that take place throughout the product life cycle from product development, equipment qualification and continuous verification of quality attributes and work instructions to product shutdown. product.

Effective validation can mean a significant decrease in cost and waste as well as increased productivity and quality assurance.

The following services can be offered:

- Process validation and improvement
- PAT (Process Analytical Technology) approach with definition of CQA (Critical Quality Attributes), CPP (Critical Process Parameters) and CMA (Critical Material Attributes)
- Definition of QTPP (Quality Target Product Profile)
- Cleaning validation

Validation of computerized systems

Computerized systems for GxP-related processes (manufacturing, quality control, warehousing, and distribution) can impact product quality, data integrity, and patient safety, therefore computerized systems must be managed within the life cycle management in accordance with GMP, Annex 11 (Computerized Systems) and 21 CFR Part 11 (Electronic Records).

Promeridian can support you totally or partially regarding the design, commissioning and validation of your computerized systems in order to provide all the documentation proving their compliance with the various GMP requirements.

The CSV (Computer System Validation) will be carried out according to the V-model of GAMP 5: planning, specification, configuration, verification and reporting. Other activities that will be covered are IT infrastructure qualification, periodic review, and commissioning/decommissioning.

ProMeridian's computerized system validation experts also provide assistance with system inventory and the establishment of a validation master plan with definition of a risk or criticality rating, validation status and a revalidation frequency

5. Research & Development

ProMeridian offers expert services in drug formulation and reformulation, analytical development and validation, technology transfer and process optimization.

Our innovative, efficient and comprehensive R&D solutions allow you to increase production yields and reduce defects, while improving your bottom line.

R&D departments

ProMeridian can assist you with the formulation and reformulation of drugs for all forms of drugs (Solids, Semi-Solids, Liquids, Injectables and biosimilars) as well as prospecting for the acquisition of drug dossiers and technology transfer.
Our expertise and capabilities are focused on the development of high value-added generic drugs and complex formulations to ensure our customers the best in technology and cost-effectiveness.

Analytical Development and Validation

The development, validation and transfer of analytical methods are key elements for any pharmaceutical development program. A well-developed analytical method can help reduce overall development time and increase profitability.
Our scientific development team can provide you with reliable methods with a high level of precision and high robustness with a combination of the assets to be analyzed in order to guarantee you a great saving of time and money. Our experts can also support you in interpreting and improving your data and analysis methods to achieve the desired improvements and performance.

Process optimization

ProMeridian experts offer continuous optimization of all processes by combining innovative and well-established technologies with intelligent solutions. All our experts are here to help you prevent downtime, increase production yields and reduce non-conformities, so you can cut costs, improve performance and achieve your objectives.

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THANKS!

For any request, contact us.

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