MFT Consult

GXP EXCELLENCE PARTNER

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2024/2025

WELCOME

Welcome to MFT Consult. We are your dedicated GXP Excellence Partner, specializing in empowering pharmaceutical and biopharmaceutical startups and new expansion projects with tailored solutions that ensure operational excellence and global compliance. Our commitment to excellence and innovation allows us to deliver world-class expertise while contributing to the localization of the pharmaceutical industry, particularly in the Middle East and Africa.

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INTRODUCTION

MFT Consult is an international consultancy firm with a core focus on providing comprehensive solutions in regulatory compliance, facility design, and quality management systems (QMS) for startups and expanding organizations in the pharmaceutical and biopharmaceutical industries. Our expertise, cultivated through years of experience working with international companies and regulatory bodies, ensures that our clients receive the highest level of service to meet both global and local standards.

ABOUT US

At MFT Consult, we specialize in guiding startups in the pharmaceutical and biopharmaceutical industries across the Middle East, helping them navigate the complexities of regulatory requirements, facility design, and quality management systems (QMS). With extensive experience working with European and multinational companies and manufacturers, our team brings global expertise to local projects, ensuring your business not only meets international standards but also aligns with the localization initiatives led by governments in the Middle East. Our goal is to enhance and empower the local pharma industry, driving innovation and ensuring global health equity.

OUR VISION

Become a leading partner for Pharmaceutical and Bio-pharmaceutical globally, with focus on the middle east and Africa, helping them achieve compliance, growth, and access to health care innovation through localized solutions and global expertise.

OUR MISSION

Our mission is to empower startups and expansion projects in the pharmaceutical and biopharmaceutical industries by providing tailored solutions in regulatory compliance, facility design, and QMS implementation. We leverage our global expertise and connections to ensure our clients meet international standards while supporting local initiatives to strengthen the pharma industry. Through collaboration and innovation, we aim to enhance quality, drive growth, and contribute to global health equity.

M. Mikhaeil Managing Director

At MFT Consult, we are committed to providing personalized, high-quality solutions that drive growth and ensure global compliance. Our success lies in empowering partners to achieve lasting impact in the pharmaceutical industry.

At MFT Consult, our team combines deep expertise in regulatory compliance, facility design, QMS, and technology transfer with the ability to act quickly and efficiently. With decades of experience in the pharmaceutical and biopharmaceutical industries, we navigate complex challenges with precision. Our work ethic is centered on integrity, innovation, and excellence. We pride ourselves on maintaining the highest standards of professionalism, consistently delivering solutions that are not only tailored to our clients' specific needs but also aligned with global regulations. Our flexible structure and strong industry connections allow us to respond swiftly to client needs, ensuring that projects are delivered on time and in full compliance with international standards.

Structure

Our flexible company structure allows us to adapt quickly to client needs, providing customized solutions and responsive service, ensuring efficient project execution and optimal outcomes.

Teams

We work with specialized teams tailored to meet the unique demands of each client, ensuring customized solutions that align with their specific needs and industry challenges.

Culture

Our company culture is rooted in collaboration, integrity, and excellence. We foster a supportive environment that encourages innovation, continuous improvement, and a strong commitment to client success.

OUR SERVICES

At MFT Consult, we offer specialized services for pharmaceutical startups and expansions, ensuring regulatory compliance, operational excellence, and tailored solutions for seamless growth.

Technical Project Management for Technology Transfer

We provide specialized project management for seamless technology transfer from development to production, ensuring compliance, quality, and smooth integration of new processes.

Regulatory Compliance & Consultation

We offer comprehensive regulatory support, ensuring compliance with WHO, FDA, and EMA standards while aligning with local regulations and facilitating market entry in the Middle East.

Facility Conceptual Design, Commissioning & Validation

We assist startups in designing and optimizing GXP-compliant facilities, from initial design to commissioning and validation, ensuring scalability for international markets and supporting local manufacturing initiatives.

Quality Management Systems (QMS)

We design and enhance tailored Quality Management Systems (QMS) that ensure global compliance while supporting the localization of pharmaceutical manufacturing in Africa and the Middle East.

ADDITIONAL SERVICES

Policy and Documentation Setup

We create and refine policies, SOPs, and documentation for a well-structured QMS, ensuring compliance with global standards and seamless integration into daily operations.

Risk Assessments & Mitigation

Our QMS implementation includes comprehensive risk assessments, addressing operational, safety, environmental, and quality risks, ensuring a proactive approach to risk management and regulatory compliance.

Environment and Safety Evaluation

We evaluate environmental impact and safety measures to ensure compliance with regulations, reducing risks when introducing new products.

Commercial and Business developments

Our Business Development Services are designed to help your company navigate the complexities of market entry, establish partnerships, and drive sustainable growth.

GMP Training

We provide comprehensive GMP training programs, tailored to startups, offering virtual, in-person, and hands-on sessions to ensure global compliance and build local expertise.

Technical Project Management for Technology Transfer

Specialized Technical Project Management services that focus on the efficient and compliant transfer of technology from development to full-scale production. Our goal is to ensure a seamless transition of processes, methods, and technologies, enabling startups and established companies alike to scale their operations while maintaining high standards of quality and regulatory compliance.

The complexity of moving from developmental stages to commercial production requires expert planning, coordination, and oversight to avoid disruptions and ensure the successful integration of new technologies and processes. Our team of experienced project managers guides you through every step of the technology transfer process, ensuring that each phase is handled with precision and in compliance with GMP and global regulatory standards.

Process Validation

We guide your team through the process validation stages, ensuring that all methods and processes perform consistently and produce high-quality outcomes at every stage of production. From design qualification (DQ) to performance qualification (PQ), we ensure that every step is validated to meet regulatory requirements

Method Validation

Our team ensures that your analytical methods are robust, reproducible, and accurate. We provide full support in method validation, verifying that all testing methods meet the requirements for precision, accuracy, specificity, and consistency across different manufacturing scales.

Project Planning and Coordination

We manage the entire project lifecycle, from planning and scheduling to execution, ensuring that all deliverables are met on time and within budget. Our team develops comprehensive project timelines and coordinates between teams to ensure a smooth transfer of knowledge and technology.

Regulatory Compliance & Consultation

Our international experience enables us to provide comprehensive regulatory support. We help your startup comply with WHO, FDA, and EMA standards, while ensuring that your business is aligned with local regulations and localization efforts in the Middle East.

We offer end-to-end regulatory support, ensuring your startup is fully compliant with international and local regulations. We guide you through every step of the regulatory process, starting from initial supplier selection to localization, ensuring a seamless pathway to market.

Supplier Selection & Evaluation
We assist with selecting and evaluating suppliers to ensure they meet the necessary standards and can support your project's requirements.

Supplier Qualification
We manage the supplier qualification process to ensure that your partners are compliant with global and local regulatory standards

Dossier Review & Submission
We help prepare, review, and submit regulatory dossiers, ensuring accuracy and adherence to guidelines for timely approvals.

Complete Regulatory Support
From supplier selection through registration to localization, we support you throughout the entire regulatory lifecycle, helping you achieve full compliance and successful market entry.

Facility Conceptual Design, Commissioning & Validation

We bring our global expertise to local markets by helping startups design and optimize their facilities to meet GXP standards.

From initial design to commissioning and validation, we ensure that your facilities are future-ready and scalable for international markets while supporting local manufacturing initiatives

- Facility design and optimization
- Commissioning and validation
- Tech transfer and scale-up support

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We provide end-to-end support, from conceptual design to commissioning and validation, for the following types of facilities:

Biopharma Production Facilities

We design and validate biopharmaceutical production facilities tailored for biologics, such as monoclonal antibodies, recombinant proteins, and cell and gene therapies. These facilities comply with stringent GMP requirements and are equipped to support large-scale, high-quality production of biologics.

Vaccine Manufacturing Facilities

Our team specializes in designing and validating vaccine production facilities, from small-scale production to full-scale commercial operations. We ensure that these facilities meet WHO and GMP standards, while optimizing to produce viral and bacterial vaccines, mRNA vaccines, and other novel immunotherapies.

Clinical Testing Centres

We provide comprehensive support in the design and setup of clinical testing centers, ensuring that they comply with global clinical research standards. These centers are designed for conducting clinical trials and testing new pharmaceuticals under controlled, compliant environments.

Bioequivalence Centres

We support the design and validation of bioequivalence testing facilities, helping startups develop centres that meet regulatory requirements for conducting bioequivalence studies, ensuring that generic products match the original brand in efficacy and safety.

Quality Management Systems (QMS)

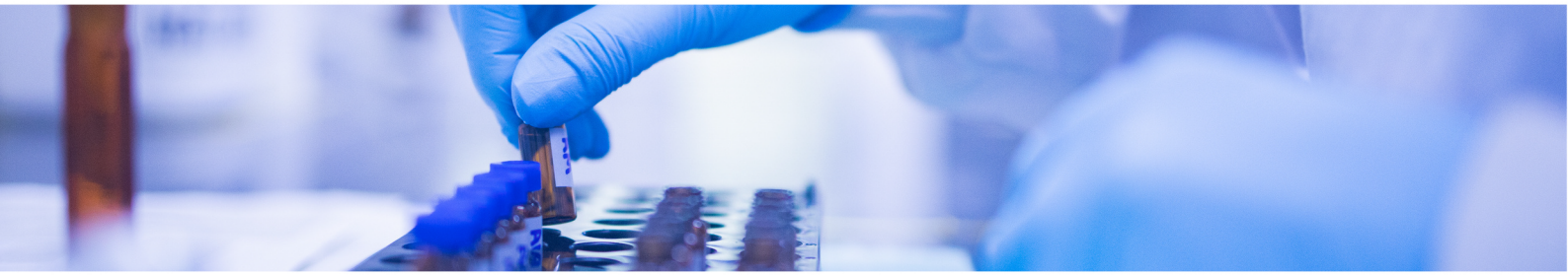
With a strong track record in international QMS standards, we help build or enhance Quality Management Systems tailored to your needs. Our solutions ensure compliance with global standards while supporting the localization of pharma manufacturing in Africa and Middle East.

QMS Design and Implementation

We work closely with your team to create a customized Quality Management System that aligns with your operational needs and ensures adherence to GMP standards. This includes setting up all required documentation such as policies, Standard Operating Procedures (SOPs), work instructions, and forms to ensure that your entire quality process is structured, traceable, and compliant. We also provide support in implementing risk assessments and evaluating environmental and safety considerations for the introduction of new products, ensuring that your facility is prepared for the dynamic nature of pharmaceutical manufacturing.

Auditing and Continuous Improvement

Our team conducts regular internal audits to identify any gaps in your QMS and provides actionable recommendations for continuous improvement. We assist in refining SOPs, improving documentation practices, and implementing corrective and preventive actions (CAPA) to ensure that your QMS evolves with regulatory and operational changes. We also support risk-based assessments, helping you identify potential quality risks and implementing mitigation strategies to prevent non-compliance issues.



QMS Design and Implementation

Our comprehensive qualification and validation support ensure that your facilities, equipment, and processes meet GMP and regulatory standards. From installation qualification (IQ) to operational qualification (OQ) and performance qualification (PQ), we validate your systems to ensure they function as intended, reducing risks and ensuring product quality. We also support your team in conducting detailed environmental and safety evaluations for introducing new products into the manufacturing process, ensuring both regulatory compliance and operational safety.

ADDITIONAL SERVICES

At MFT Consult, we provide comprehensive QMS support, including policy setup, risk assessments, and safety evaluations. Our tailored solutions ensure global compliance, minimize risks, and integrate seamlessly into your day-to-day operations.

Policy and Documentation Setup

We help establish the full range of required documentation for a compliant and well-structured QMS. This includes creating and refining policies, SOPs, work instructions, and supporting documentation that align with global standards and can be integrated into day-to-day operations.

Risk Assessments & Mitigation

Our QMS implementation includes detailed risk assessments for both operational and product-related risks. This includes safety, environmental, and quality risks, ensuring you have a proactive approach to managing risk and meeting regulatory requirements.

Environment and Safety Evaluation

We evaluate your facility's environmental impact and safety measures, particularly when introducing new products. This process ensures that both environmental regulations and occupational health and safety standards are met, reducing risks and ensuring compliance with international regulations.

Commercial and Business developments

Expanding pharmaceutical and biopharmaceutical companies not only need regulatory and quality management support but also strategic guidance to grow and scale their businesses. Our Business Development Services are designed to help your company navigate the complexities of market entry, establish partnerships, and drive sustainable growth. We provide comprehensive support that aligns business goals with operational capabilities.

Market positioning

Through assisting in developing commercialization strategies for new products, from positioning and pricing to go-to-market plans. Our goal is to help you maximize the commercial potential of your products while meeting regulatory requirements.

Partnerships and network

Leveraging our extensive network, we help identify and establish strategic partnerships and alliances that align with your growth goals.

Market entry strategies

We assist in developing tailored market entry strategies. This includes understanding regulatory landscapes, market needs, and competitive positioning to ensure a successful entry and growth.

Training Programs

We offer training programs to develop your commercial team's skills in sales, marketing, and customer relations.

GMP TRAINING

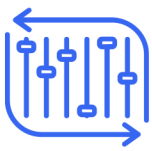
We offer comprehensive GMP training programs designed to empower startups and their teams with the knowledge and skills needed to operate in GMP-compliant environments. Our training programs are suitable for startups looking to establish solid GMP foundations and professionals seeking to refresh and update their knowledge of Good Manufacturing Practices. Our virtual, in-person, and hands-on training solutions are built around the latest industry regulations and tailored to meet the unique needs of each startup, ensuring compliance with global standards while fostering local expertise.

Virtual and In-Person Training

We offer both virtual and in-person training options to provide flexibility and convenience. Whether participants engage remotely or in a classroom setting, we ensure that they acquire the critical skills needed to support GMP compliance in a pharmaceutical environment.

Hands-On Training at European Facilities

In addition to virtual and in-person training, we offer the possibility of coordinating hands-on training at European manufacturing and testing facilities. This immersive experience allows participants to work directly in GMP-compliant facilities, gaining practical skills in manufacturing processes, testing, and quality control. By training in a real-world environment, participants get valuable insight into European manufacturing and testing standards, which can be applied to their local operations.



Customizable Training Programs

We understand that every startup has unique challenges, which is why our GMP training programs are fully customizable. We work closely with your team to tailor the curriculum, focusing on specific topics such as quality systems, deviations, change control, OOS, and documentation, providing practical solutions to your operational needs.

Certificates Upon Completion

Upon completing the program, participants receive a GMP certificate, which validates their understanding of GMP principles and best practices. This certification is a valuable asset, demonstrating their capability to operate in GMP-compliant environments and supporting professional development. Certified teams are better prepared for regulatory inspections and audits.

WHY CHOOSE OUR GMP TRAINING?

Expert-Led Instruction

All of our programs are led by experienced industry professionals with extensive knowledge of GMP and pharmaceutical manufacturing.

Hands-On European Training opportunities

We coordinate and plan immersive, hands-on training sessions at European manufacturing and testing facilities, allowing participants to gain real-world experience in operating within GMP-compliant environments.

Tailored Learning Experience

We offer customized programs to address your unique operational challenges, ensuring practical and relevant training.

EXCELLENCE ACCROS REGIONS

GLOBAL EXPERTISE AND LOCAL IMPACT

At MFT Consult, our global reach and local expertise allow us to serve pharmaceutical and biopharmaceutical startups and expansion projects across a wide range of regions. While our headquarters are based in Europe, we have a strong focus on providing tailored solutions in the Middle East, Africa, and beyond. Our deep understanding of both international regulations and local market dynamics enables us to deliver customized, compliant solutions that meet the unique needs of each region.

In the Middle East, we support the growing pharmaceutical sector by helping clients navigate local regulatory requirements while aligning with global standards such as WHO, FDA, and EMA. We play a key role in the localization of pharmaceutical manufacturing, ensuring that companies in the region are prepared for global compliance.

In Africa, we empower startups to build world-class facilities and implement robust Quality Management Systems (QMS), helping to elevate local industries to meet international standards. By offering our expertise in regulatory compliance, facility design, and technology transfer, we contribute to the region's pharmaceutical development and growth.

Beyond these core regions, our global experience enables us to work with clients from all corners of the world. Whether you are in Europe, the Middle East, Africa, or other emerging markets, MFT Consult brings the right blend of global insights and local understanding to every project. We are dedicated to helping our clients achieve operational excellence and regulatory success, no matter where they are located.

OUR VALUES

At MFT Consult, our core values form the foundation of everything we do. Like an umbrella, they provide comprehensive coverage, ensuring our clients are protected, supported, and empowered to thrive in the pharmaceutical and biopharmaceutical sectors. These values guide our approach, offering a shield against challenges while fostering collaboration and innovation. Under this umbrella of excellence, we deliver tailored solutions that meet the unique needs of every client, helping them achieve success in a complex, ever-evolving industry.

Reliable Coverage

We offer a broad, end-to-end services that cover all critical aspects of your project. From compliance to facility design, our expertise ensures nothing is overlooked, providing you with full, reliable coverage

Excellence

We are committed to delivering precise, high-standard services in every project. From compliance to facility design, we aim to exceed expectations through meticulous attention to detail and a pursuit of operational excellence.

Collaboration

We uphold transparency, honesty, and accountability in all we do. Our clients trust us to deliver compliant, high-quality solutions, and we always prioritize their long-term success by fostering open communication ensure mutual growth and success.

Innovation

We embrace new technologies and methods to stay ahead in the pharmaceutical industry. Innovation drives our ability to adapt, improve compliance, and support client success in a constantly evolving landscape.

THANK YOU

We sincerely thank you for taking the time to learn more about MFT Consult and our approach to delivering excellence in the pharmaceutical and biopharmaceutical industries. At MFT Consult, we are committed to building long-lasting partnerships based on trust, integrity, and shared success. We value the opportunity to be a part of your journey, and we look forward to supporting your business with our tailored solutions and industry expertise.

Warm regards,

MFT Consult

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