



INTRODUCING

COMPASS
by FAMAR



FAMAR proudly launched its new services business unit, COMPASS by FAMAR, during a LIVE Web Event, in the presence of strategic customers, partners and guest speakers.

With this launch, FAMAR innovates, positioning COMPASS by FAMAR as the first CSCO - Contract Services & Consulting

Organization, opening a new market segment to combine the extended industrial experience of a CDMO with the agility to offer ready-to-use solutions for Technical, Analytical and Quality Compliance Operations.

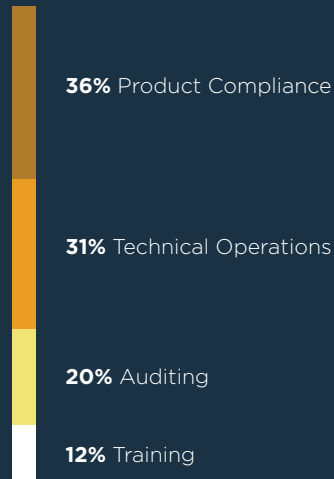
During the exclusive LIVE Web Event, COMPASS by FAMAR offerings were presented in detail giving insight on how the CSCO advisory model is structured. Esteemed speakers joined LIVE panel discussions to elaborate on the several advantages of having a CSCO partner and how COMPASS by FAMAR helps companies navigate when facing challenges in technical, analytical and quality compliance segments.

THE MARKET NEED

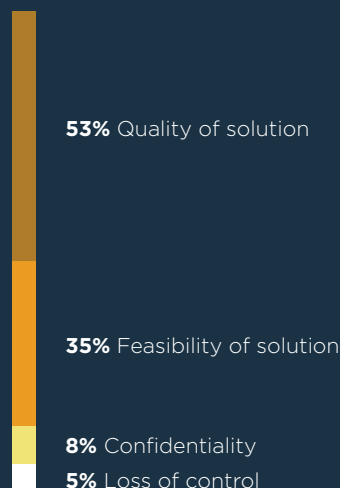
Recent research¹ showed that there is a significant growth in the segment of outsourcing Quality Consultancy Services with the prevalent segments of Operational Technical Quality Assurance Services, Analytical Testing, Auditing and GMP/GDP Remediation as well as, Regulatory Intelligence Services.

In addition, market polls indicated that the most valuable outsourced services in the Pharmaceutical industry relates to Product Compliance as well as, Technical Operations followed by Auditing. However, It is also attested that more than often, pharmaceutical companies struggle to find a fit technical advisory service provider that can offer hands-on, high quality solutions on industrial operations.

Which is the most valuable outsourced Service for your business in the Pharmaceutical sector?



What is most challenging in receiving technical consultation services & solutions in the Pharma Manufacturing Business Segment?




¹Grand View Research (2022) U.S. & Europe Healthcare Quality Consultancy Services



FINDING YOUR COMPASS

COMPASS by FAMAR, addressed this unmet market need, offering solutions proven to work in own FAMAR sites, developed by Subject Matter Experts that are currently field-active and with proven experience in the complex CDMO industrial operations.

Services are offered to medium and small Pharmaceutical companies in need of “ready to use” industrial solutions, as well as, large Pharmaceutical companies in need to supplement their capacity in technical operations or product compliance services, with a strategic and reliable outsourcing partner. In addition, **COMPASS by FAMAR may serve as a “one-stop-shop” for Pharma and Bio Pharma startup** firms that may not have the knowhow or infrastructure to design and integrate a robust Quality Management System.



**COMPASS by FAMAR
offers its agile services structured
in the following segments:**

ANALYTICAL SERVICES

- Stability Study Design, Storage, Testing & Product Trend Statistical Profiling
- Chemical & Microbiological Analysis for raw materials, intermediates and finished products, Method Development, Optimization and Validation
- Analytical Laboratory Investigations
- LeanLab Models to boost QC laboratory efficiency

INDUSTRIAL SERVICES

- QP Services for EU batch release and QP declarations
- GMP/GDP Due Diligence structured under a 6-Systems Inspection Model
- Integrated Contamination Control Strategy for sterile manufacturing sites
- Operational Excellence models for industrial manufacturing efficiency
- Environmental Monitoring, sampling protocols, risk assessments, samples collection & data trending.
- Quality Engineering Lifecycle Management and Validation/ Qualification Strategy Design for Facilities, Systems, Utilities, & Equipment
- Product Lifecycle Compliance Management Reports i.e. Product Quality Reviews, Ongoing Process Verification (CPV) Statistical Design Process Robustness Reporting, Product Compliance Risk Assessments (Nitrosamines, Elemental Impurities etc.)

REGULATORY SERVICES

- Regulatory Intelligence with global governance on legislative developments and impact analysis on industrial operations.
- Regulatory Affairs on CMC gap analysis, CTD upgrades and market extensions.



QUALITY MANAGEMENT SYSTEMS

- Quality Management Systems' Design
- Quality Management Systems' Digital Transformation
- Quality Contracts negotiation strategy and ready to use QTA templates
- Inspection Readiness programs for EU and international inspectorates
- Supplier Compliance program for governance, risk management and surveillance of all types of GxP suppliers and service providers
- Training Academy modular learning sessions on a variety of industrial and Quality Management disciplines



CHOOSE YOUR PATH!

WHAT WE DO DIFFERENTLY

COMPASS by FAMAR offers advisory services and applied solutions never before offered by a CDMO into a technical consultancy scheme. This is why we proudly position ourselves in the Pharma Industry as the founders of this new business segment we call CSCO - Contract Services & Consulting Organization.

Our name, annotates the services provided in Contract Operations for Manufacturing, Packaging, Analytical, Solutions & Services - but more so, it denotes the journey to be chosen when a company selects our services.

The COMPASS by FAMAR advisory journey is tailored made, focusing on the challenges to be addressed towards the end solution implementation. Under the CSCO partnership, this is a path the teams pave together, while the SMEs guide like a compass, using their extensive expertise to help customers avoid inefficiencies and compliance risks.



KEY STATIONS ALONG THE ADVISORY JOURNEY INCLUDE:

Project Scoping: Key focus on the importance to capture the customer needs, constraints, strengths, concerns and operational particularities, as these drive the path to be chosen and impact the integration design of the end solution.

Team Assembly: Under the principles of Agile Organization Management, a team of empowered COMPASS by FAMAR Subject Matter Experts is organized to deliver high quality standards with accountability, transparency, and team work, while adapting the ready-to-use solutions to the needs and circumstances of the local operational units.

Engagement: Hands-on collaboration is a key driver for the journey. Workshops are designed and delivered to target local teams' engagement and collaboration, for the end results to be owned by the local organization. This is the only way to reach the designed destination in a sustainable manner.

Deliverable Objectives & Key Results: Setting objectives and Key Results is integral for local teams to be able to evaluate their effectiveness and monitor the efficacy of the solutions applied.

Sustainability: The adapted solutions are fully integrated into the local Quality Management System and owned by the local organization. As such, when the advisory journey is completed and the designed end result delivered, the local teams are on steady path to sustain it.

OUR CUSTOMERS SAY ABOUT US

“

*A different view
of consultancy in
Pharma*

“

*Hands on
experience, at last!*

“

*“COMPASS by FAMAR
is a trustworthy, reliable
partner for us”*

