BIO15PHARMA

Consulting firm specialising in Quality Management and GxP Compliance

Expert in Pharmaceutical Interim Management

- PHARMACY
- CHEMISTRY
- COSMETICS
- MEDICAL DEVICES
- BIOTECHNOLOGY
- CRO

How can we improve the manufacturing practices for medications and active ingredients ?

Since 2015, businesses in the pharmaceutical sector have been faced with many ANSM and FDA injunctions. The one commonality between these orders has been Quality Management System failure and/or significant negligence of Good Manufacturing Practices (GMP).

These requirements also impact all players who are connected to the medical sector : chemicals companies, cosmetics, medical devices, CRO, and biotechnology companies.

The goal : ensure product quality

In order to guarantee patient safety, it is necessary to put in place a robust, homogenous Quality Management System (QMS), with simplified processes, and to comply with the GxP guidelines.

BIO15PHARMA seeks to address these needs by offering top-tier services to ensure product quality and provide effective QMS to the life sciences industries.

Regardless of your company's size, BIO15PHARMA can intervene at different levels : Transition management, management of strategic projects, crisis management to follow up on an order, change management relating to Quality and GxP compliance processes.

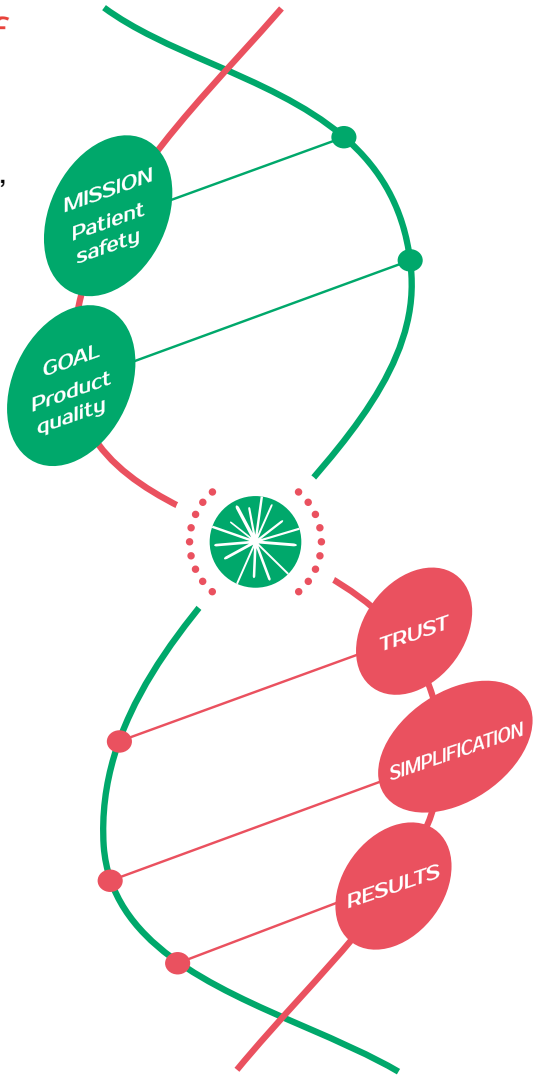
Our realms of expertise :

- ✓ Transition management in the areas of Quality Management Systems, GxP compliance, regulatory affairs, pharmacovigilance, and clinical research.
- ✓ Simplification of Quality Management Systems (QMS)
  - Quality assurance
  - Quality control
  - Sterility assurance
  - Data Integrity
  - Inspections/Audits
  - Management of ANSM, FDA, and ANVISA orders
  - Qualifications - Validations
  - Training
- ✓ Simplification of the Regulatory Affairs Management System
  - Dossiers for Authorisations to Open a Pharmaceutical Establishment
  - Marketing Authorisation Dossiers, etc.
- ✓ Simplification of Pharmacovigilance Management Systems
  - Gap analysis of QMS with respect to Good Pharmacovigilance Practices
  - Process mapping and continuous improvement, etc.
- ✓ Implementation of electronic quality management systems (EDM, EBR, eCRF, etc.)
- ✓ Simplification of Management systems for Phase I, II, and III clinical trials

Our highest commitment :

Putting the patient at the heart of all of your processes

We will help you move all of your projects forward with an innovative, personalised, expert approach that is wholly patient-centred.



BIO15PHARMA's business DNA is made up of 6 core values :

- ✓ Trust between all parties,
- ✓ Employee involvement,
- ✓ Patient safety,
- ✓ Team responsibility,
- ✓ Process simplification,
- ✓ Satisfaction with results

A results-oriented approach :

✓ **Handling your emergencies**

Bringing on board Transition Managers in 24 hours.

Piloting quality projects and proposing a quality plan to follow up on an inspection or a self-inspection.

Managing crises that arise from orders so as to lift the order and continue manufacturing, certification, free up batches, and market products again.

✓ **Simplifying your processes**

Taking charge of change management in order to refine or improve the QMS and the GxP.

Correcting gaps identified during inspections and/or internal audits.

Deploying a training and authorisation system for your employees.

✓ **Securing your business**

Carrying out GxP compliance projects to guarantee high quality products that are pure, efficacious, and not harmful to patients.

Putting in place personalised systems for Electronic Document Management (EDM) and Electronic Batch Records (EBR).

Deploying personalised digital solutions to remotely manage inspections and audits.

Putting in place monitoring management systems and fill volume control systems.

About BIO15PHARMA

BIO15PHARMA was founded by Nadjim Mhoma, its current director.

Over the course of 12 years of experience in the pharmaceutical, chemical, cosmetic, medical device, and biotechnology industries, and helping CROs, Nadjim Mhoma has worked as the Director of Transition with Impact and as a Director of Quality & Regulatory Affairs and a Clinical Research Associate.

Co-founder of IMWI, Nadjim Mhoma is also a certified Quality Safety Environment Auditor.
In this capacity, he has led ISO 14001 and OHSAS 18001 certification projects and put in place digital solutions (EDM, EBR, eCRF, etc.).

Education :

ESCP Europe, Paris: Executive Master's in Management (MBA).
CESI, Rouen: Master's specialising in Quality Safety Environment Management.
University of Rouen: Undergraduate Degree in Biochemistry.
École Polytechnique: Undergraduate Degree in Chemical Engineering.

Our partners :

Client references :

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