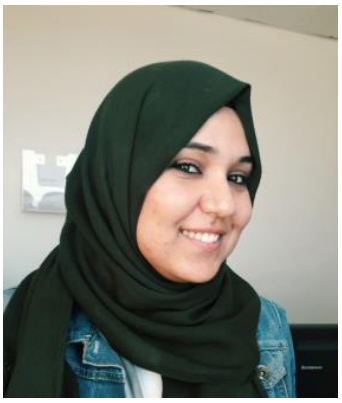
Marwa CHALBI Quality Assurance Manager



EDUCATION

2014-2016	Professional Master, Speciality : quality control of health products - Higher Institute of Biotechnology Sidi Thabet
2011-2014	Applied License in Analytical and Experimental Biology, speciality : «Analysis and quality» - Higher Institute of Biotechnology Sidi Thabet
2011	Scientific Baccalaureate, speciality: experimental sciences

TRAINING

February – December 2017	Final project of Professional Master in the pharmaceutical industry MEDICEF on the application of quality tools (FMEA machine, six sigma, Pareto, 5M, etc.) in order to minimize the cost of sorting in a primary and secondary packaging line.
June – 2015	Training in the laboratory of microbiology in the pharmaceutical industry MEDICEF.
February – May 2014	Final project of Applied License in the National Institute of the Agricultural Research of Tunis on the proliferation of two varieties of cacti.
June – 2013	Training in the laboratory of biological analyzes of Tabarka hospital.

WORK EXPERIENCE

December 2019 – Currently : Quality Assurance Manager at Galien Pharmaceuticals

- Apply the Good Manufacturing Practices (GMP) requirements and quality assurance rules.
- Regularly assessment of the effectiveness and the application of the quality assurance system;
- Propose and manage the quality improvement projects;
- Manage and follow the change controls, the non-compliances and the deviations;
- Develop the document management policy;
- Create, Verify or Approve the procedures, instructions and specifications;
- Supervise the training of technical management staff ;
- Propose and provide the training on good manufacturing practices;
- Supervise and control the manufacturing environment;
- Follow the qualification, validation and metrology activity;
- Manage the staff of the Quality Assurance department

November 2017- December 2019 : Document Manager Quality Assurance at Sanofi Site of Megrine Tunisia

✓ **Management of The Documentary System**

- Design of document management methods mainly the archiving charter and operation of the document management system.
- Fluidify the document management processes in order to improve and control the entire life cycle of the document, from its creation until its archiving and its possible destruction at the end of the legal retention period.
- Documentation Harmonization Project: implementation of site document frameworks

CONTACT

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SKILLS

Rigorous/ Dynamic
Methodical/ Team spirit
Analytical and listening skills
Good communication

TRAINING

GMP : Good Manufacturing practices
Data Integrity
Human Error Prevention

HOBBIES

Clubs and associations of social and cultural interest
Member JCI
Sports

✓ **App Administration GEODE+**

- Administer and Manage the application GEODE+ (doc Manager)
- Organise and coordinate the training on the application GEODE+
- GEODE+ application access management
- Project simplification of master manufacturing files

✓ **Implementing Documents GQD**

- Implementation follow-up of gap analyzes between the GQDs and local documentation
- Implementation of a governance system to ensure compliance of Sanofi quality documents with group quality requirements and GMP in force and improve site KPIs

LANGUAGES

Arab

French

English

Italian

ADDITIONAL FUNCTIONS

- Establishment of governance systems to improve the documentation and management system of **CAPA and EVENT**
- Achievements of the periodic **quality self-inspection** to ensure a good understanding of the quality approach through compliance with instructions, procedures and guidelines.
- Preparing for the **ministry inspection** and **Global Quality Audit**
- Participation in the **Gemba Walk** in the site's production workshops, implementation of daily reporting Verification of the implementation of CAPAs
- writing of Quality SOPs
- Participation in the development of LEAN tools and SMS Job : **TIP100 et +QDCI**
- Role of the Backroom manager for the GQA audit
- Script role for GKF inspection
- Participate in the implementation of the training program in Good Manufacturing Practices
- Achieve the training GMP program of all the staff.

TECHNICAL KNOWLEDGE

- ✓ MS Office (Excel Word PowerPoint …)
- ✓ Platform software of SANOFI: GEODE+ ; PHENIX
- ✓ Knowledge of quality tools: AMDEC, 5S, 5M, Brainstorming, QQOQCCP, PDCA, self-inspection, CAPA
- ✓ Recognition of applicable standards in the pharmaceutical and agri-food sectors : ISO 9001, ISO 17025, ISO 15189, ISO 22000, ISO14001, GMP
- ✓ Training required: ISO 17025
- ✓ Training required: GC/MS/MS à Ion Trap Agilent
- ✓ Hygiene and safety rules.