



Network of Universities
from the Capitals of Europe



Maaïke Gons

**Quality Assurance
Data Integrity Officer**



The organisation at Sanofi



Specialty Care

- Immunology
- Neurology / Multiple Sclerosis
- Oncology
- Rare Diseases / Hematology



General Medicine

- Cardiovascular diseases
- Diabetes
- Established Products



Vaccines

- Pediatric vaccines
- Influenza Vaccines
- Adult booster vaccines
- Meningitis vaccines
- Travel vaccines and endemic areas



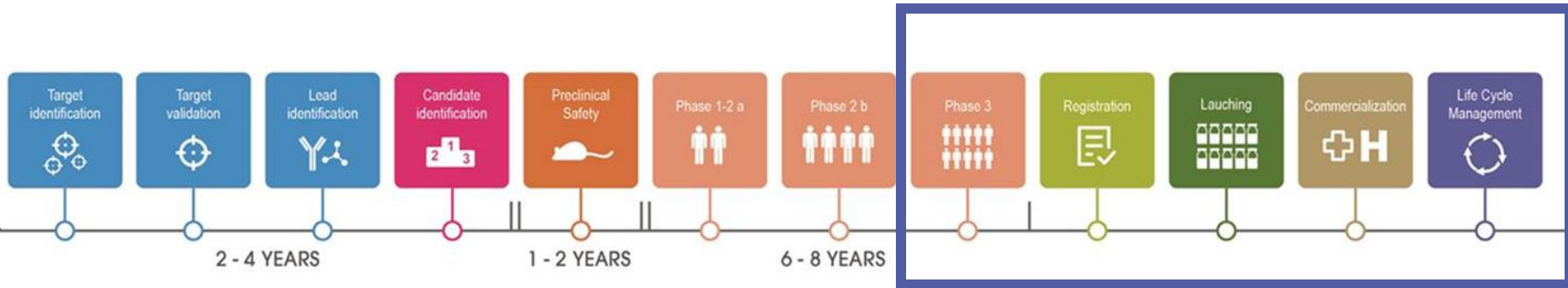
Consumer Healthcare

- Allergy, Cough and Cold
- Pain
- Digestive health
- Food supplements

QUALITY ASSURANCE ON A MANUFACTURING SITE



LIFE CYCLE OF A MEDICINAL PRODUCT



What is quality assurance?

QA ensures products and services are reliable and fit for purpose.

Building quality by design results in purity, safety, efficacy, quality of the products

In manufacturing : ensure products are manufactured, stored and packaged in accordance with Good Manufacturing Practices



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Principles and guidelines applied at a manufacturing site



Pharmaceutical
Quality System



Personnel



Premises and
equipment



Production



Quality Control



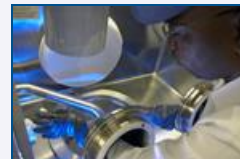
Documentation



Outsourced
activities



Complaints and
product recall



Self inspection

Basic requirements



Site Master File



Quality Risk
Management

Key documents

QUALITY ASSURANCE – LOCAL ORGANISATION

RESPONSIBILITIES

QA SYSTEMS

- SOP & Documentation Management
- Data Integrity Governance
- GMP Training / Supplier Audits & Management /Specification Management
- Deviation, Change Control, Complaint System
- Site Quality Reviews
- Organise Audits & Inspections

RESPONSIBILITIES

REGULATORY SITE

- Regulatory compliance
- Submission of Variation files / Annual report to Health Authorities
- Change control / registration / regulatory assessment
- Technical documentation for partners/customers
- Site Master File
- Master Documentation Certification (Production, Analytical Methods)

RESPONSIBILITIES

OPERATIONAL QA

- Quality oversight of operations
- Batch Record Management & Release
- Deviations / Investigations / CAPA / Change control
- Annual Product Quality Review
- Approval of product specifications
- Documentation
- Quality oversight on Process Validation

RESPONSIBILITIES

QA BIOCOMPLIANCE

- Ensure microbiology and viral expertise in process and analytics, including in validation
- Coordinate and ensure trend analysis of environment and clean utilities data
- Define control strategy to prevent any contamination risks
- Coach operations on contamination control requirements

RESPONSIBILITIES

QA GMP COMPLIANCE

- Responsible for identifying gap in site practices and documentation against cGMPs to drive compliance
- Train & develop personnel in order to reach and maintain "Inspection readiness"
- Coordination of site inspection readiness towards completion of site registration by NHA
- Management of self-inspection program



Career development

Education & skills

EDUCATION - EXEMPLES

- **Engineering**
- **Life sciences**
- **Pharmacy**
- **Biology/microbiology**
- **Masters in Quality Assurance/Quality management**

WHAT SKILLS DO WE LOOK FOR?

- **Critical thinking skills**
- **Analytical/problem-solving skills**
- **Rigor**
- **General interest**
- **Care for the patient**
- **Passion for process improvement**
- **Influencing skills**
- **Communication**

How did it work out for me?





SANOFI
Empowering Life

THANK YOU

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