C.G.F.E

Pharmacist with 20 years of experience in pharmaceutical industry. Specialized in quality with QP responsibilities in Pharma, Generics and Consumer Health business company

SKILLS

- EU GMP and Swiss Regulations
- Ability to work in international environment
- Communication with Heatlh Authority
- Experienced with foreign HA (France,Switzerland,Russia, Brazil, Korea)
- Team Leader
- Able to work under pressure
- Result oriented and customer oriented
- Reliable

EXPERIENCE

- **QA Release, Compliance & Auditing Senior Manager / QP**
  GSK Nyon (Vaud), Switzerland
  May 2018 – Present

  - Staff Managed: 15 people

  - Budget: 2 million £

  - **Batch Release** : Management of batch release team. Responsible Person (QP) for release of finished products and API production batches. More than 7500 batches released per year. Process improvement to reach 2 days as batch release lead time

- **Quality Management System** : Responsible for GMP documentation, implementation of Corporate QMS at the site, Site Quality Council, Risk Management System, lead for site quality initiative (i.e.: Deviation reduction program, inspection readiness, …)

- **Audit** : Responsible for internal audit plan, external audit of local supplier / service provider and host for inspection and corporate audit

- **QA Supplier** : Responsible for QA supplier management (100 suppliers of API, raw materials and packaging materials and 80 service providers). End to end process quality overview from selection / approval of suppliers to vendor complaints and supplier monitoring

- **QA Release & Product Surveillance Manager / QP**
  GSK Nyon (Vaud), Switzerland
  March 2015 – May 2018

  - Staff Managed: 25 people

  - Budget: 2,5 million £

  - **Batch Release** : Management of batch release team. Responsible Person (QP) for release of finished products and API production batches. More than 7500 batches released per year. Process improvement to reach 2 days as batch release lead time

  - **Product stability & QC Validation :** Management of product stability team and QC validation team in charge of analytical method validation, transfer in and out, testing of validation samples (process and cleaning validation)

  - Product Quality Review

  - Customer Complaint

- **QA Batch Release Manager**
  Novartis Nyon (Vaud), Switzerland
  Nov 2012 – March 2015

  - Staff Managed: 3 people

  - **Batch Release**: Building release team and batch release process for raw materials, finished products and API production batches. More than 6000 batches released per year.

- **Head of Quality/ QP**
  TEVA Santé Sens (Yonne), France
  July 2002 – Nov 2012

  - Staff Managed: 20 people

  - Budget: 1,2 million €

  - **Batch Release** : Management of batch release team. Responsible Person (QP) for release of bulk and finished products batches. More than 3200 batches released per year (65% produced by contract

manufacturers). Process improvement to reach 3 days as batch release lead time and efficiency increased (+ 30% in 5 years)

- **Quality Management System** : Responsible for GMP documentation and GMP training, implementation of Corporate QMS at the site, dashboard and reporting, Site Quality Council, lead for site quality projects, customer complaints, internal audit and host for inspection, corporate audit and customers audit

- **QA Supplier** : Responsible for QA supplier management (60 contract manufacturers in Europe). Quality overview from selection / approval of suppliers (audit and quality agreement) to product quality issue handling

- **QC Lab and post-marketing stability** : Team management, budget, investment, improvement QC lead time

- **QA Pharmacist / QP deputy**
  Bayer Pharma Sens (Yonne), France
  Sept 1999 – July 2002

- **QA Supplier** : Responsible for QA supplier management (60 contract manufacturers in Europe). Quality overview from selection / approval of suppliers (audit and quality agreement) to product quality issue handling

- **Quality Management System** : Responsible for GMP documentation and GMP training, deviation in production, quality council

- **Packaging Material** : Artwork approval, sampling, testing and release of packaging material batches and vendor complaint handling

EDUCATION

2000 : Pharmacy Doctor
University Paris V
Thesis "Cleaning validation of mixer, granulator, dryer and containers used for production of Atenolol tablets"

1997-1998 : D.E.S.S Quality Assurance of Medicinal Products
University Paris V
(Pr. Chemtob)

1996 : Master's Certificate
University Paris V
« Bioavailability of medicines »
(Pr. Brossard and Pr. Chaumeil)

1995 : Master's Certificate
University Paris V
« Physical and chemical aspects applied to pharmaco-technical innovation"
(Pr. Chaumeil)

LANGUAGES

- French : Mother tongue
- English : Fluent