Quality Management

Experience

- **Quality Control (QC) tasks and results from Pharmaceutical Industry include**
  - Full GMP compliance was met i.e. all analyses were according to Pharmacopeia Methods, primarily, but not exclusively USP (United States) and Ph. Eur (European)
  - CC (Change Controls), OOS (Out of Specification), OOT (Out of Trend), Deviations and CAPA's were handled according to GMP regulations in the TrackWise System
  - Specifications were very complex due to many Customer specific requirements to be fulfilled
  - Visual control of packaging materials (both as ingoing and Finished Product control)

- **QC tasks and results from Biotech Industry include**
  - QC knowledge of quality requirements for analytical methods for enzyme analyses
  - Development and implementation of Analytical Method Database on MS SharePoint
  - Automation of manual handling procedures in lab: I.e. participated in implementation of robots for dilution processes and automatic weigh out
  - Insight in DoE (Design of Experiments) in SAS JMP and ANOVA (Analysis of Variance) analyses
  - LEAN procedures in QC

- **Quality Assurance (QA) manager with extensive product quality responsibility including**
  - Handling of Quality Questionnaires from customers relating to all aspects of Quality using CRM integrated in Outlook, all were finalized in a timely manner
  - Participated in investigations related to customer complaints and handled everything related to Quality, CRM was used
  - Customer agreements were finalized in collaboration with Sales in CRM
  - Daily support to Production and specification updates in SAP
  - Handling of stability data
  - Optimization projects completed included
    - Reduction of enzyme dust in production
    - Investigation of allergen carry over in production lines
    - Establishment of germicidal effect of specific products.

- ⇒ Conversion of internal SOP's for analytical methods to Customer versions, this required large insight and understanding of the analytical methods and principles.
- ⇒ Insight in and fulfilment of the special requirements needed for the Asian Markets, especially China and South American Markets, especially Brazil

⇒ **Implementation of ISO 13485 for Medical Device – consultant support is offered**

Kalsbeek Consult ApS can assist with

- ⇒ QC and QA tasks as described in Experience above
- ⇒ Assessment of required Quality Management system, gap analysis and implementation
- ⇒ General quality support
- ⇒ Implementation of ISO 13485 and advice on MDR 2017/745 (Medical Device Regulation) and IVDR 2017/746 (*In Vitro* Diagnostics Medical Device Regulation)
- ⇒ Tasks abroad are of interest, Danish, Dutch and English are my main languages

Contact and More Information

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