

# 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
    - ⇒ 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.
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- ⇒ 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

## Kalsbeek Consult 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
- ⇒ Tasks abroad are of interest, Danish, Dutch and English are my main languages

## Contact and More Information

Please take contact for any questions or comments by

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