Strategic expert in clinical and scientific affair field, with a successful experience in management of projects and teams

## SKILLS HIGHLIGHT

TECHNICAL SKILLS:
GCP trained
Microsoft Office

SOFT SKILLS:
Good management skills
Good communication and coordination skills

## TRAINING

EDUCATION:
Post-Graduation in Clinical Research

- **Bachelor of Pharmacy**

CERTIFICATIONS:

**GCP training**

## Language

- **English: fluent**

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## PROFESSIONAL EXPERIENCE

### TITLE: DIRECTOR, CLINICAL DEVELOPMENT

**Field of activity: pharmaceutical products / consulting company**
Dates: 09/2015 – current

**MAIN RESPONSIBILITY**

Leading team of scientific affair and responsible for development of clinical strategy of drugs from phase 1-3 as well as CTD module writing activities for regulated markets-US, EMA, WHO, etc

**ACTIVITIES PERFORMED**

- Design overall clinical development program in compliance with ICH GCP and applicable regulatory requirements of proposed markets especially for EU and US for various therapeutic segments for complex generics, biosimilars, biologics and NCEs.
- Due-diligence activities for clinical/non-clinical data
- Represent Clinical and non-clinical expertise at the scientific advice meetings with the health authorities in USFDA, EMA, MHRA, and WHO.
- Management of pre-clinical and clinical studies required for marketing authorization in EU, US and ROW.
- Review and finalization of CTD modules, ERA, PDE reports, clinical trial documents, ODD dossiers, scientific justifications, etc.
- Strategizing and executing end to end product development from pre-clinical to the marketing authorization phase for complex generics, biosimilars, biologics and NCEs.

### TITLE: MANAGER, GLOBAL CLINICAL OPERATIONS

**Field of activity: Medical Devices**
Dates : 2013-2015

**MAIN RESPONSIBILITY**

Responsible for development of clinical strategy of medical devices from phase III and IV for regulated markets-EU and ROW

**ACTIVITIES PERFORMED:**

- Design and execution of the overall clinical development program in compliance with ICH GCP and applicable regulatory requirements of proposed markets especially for EU and ROW.
- Clinical trial operations management for Global clinical trials for medical devices (Coronary Stents)
- Conducting visits to Global sites for Site initiation and Site monitoring activities
- Responsible for deliverables to be completed within the time scales
- Leading team of 15 clinical operations experts.

### TITLE: SENIOR MANAGER, CLINICAL TRIALS

**Field of activity: Global pharmaceutical company**
Dates: 2007-2013

**MAIN RESPONSIBILITY**

- In charge of leading the scientific affairs department

**ACTIVITIES PERFORMED:**

- Involved in Clinical Due-diligence activities for selection of Biosimilar co-development partners.
- Involved in designing clinical and pre-clinical strategy for conventional formulations, NDDS, and for Biologics.
- Involved in design & execution of the overall Clinical and Preclinical development program for conventional formulations, NDDS, and for Biologics in compliance with ICH GCP and applicable regulatory requirements of proposed
- Lead team of scientific affair and scientific medical writers.