Kirtida Rana

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Someone at somewhere

Regulatory Experience (in general):

- As a regulatory head,
  - Closely worked with RAPS approved person for technical dossier preparation and with renowned experts for establishing and monitoring of quality management system.
  - Frequent meetings with state regulatory laboratory for issues related to microbiology culture such as its growth, identification of limits etc.
  - Close interactions with state/zonal/national regulatory officers for ongoing assignments.
  - Established good rapport with prime certification bodies for CE marking.
  - Regular meetings with medical professionals and patients for feedback on product usage
  - Conducting cGMP and ISO audits as an external advisor
  - Preparation and submission of regulatory applications

- As a plant head,
  - Set up the medical device manufacturing facility that includes various approvals from regulatory agencies, construction and building of clean room, procurement of equipment and instruments, process validation, equipment qualifications, manpower recruitment and so on.
  - Site visits for supplier selection and approval
  - Active participation for GMP, GLP, QMS audit training courses
  - Providing active learning and on site assistance for cGMP and QMS
  - User manual and promotional literature preparation including translation in local (Indian) languages

Regulatory Experience (device specific):

- Development and validation of
  - Drug-device combination product and relevant processes
- Evaluation of CROs for animal study of
  - Cardiac implants
- Coordination for a research project on
  - Drug-device combination product
- Coordination for conducting biocompatibility studies of
  - Drug-device combination product
- Coordination with an NRA laboratory for Pharmaco-kinetic study of
  - Drug-device combination product
- Post market surveillance of
  - Imported cardiac implants
- Drafting stability study and clinical trial protocols for

    - Drug-device combination product
- Development and implementation of bar code for labelling of
    - Cardiac implants
- Clinical evaluation report of
    - Abosrbalbe Sutures
    - Cardiac implant

History of successful assignments:

- CE marking of
    - Cardiac implants
    - Syringes
    - Surgical laser
    - Ophthalmic implants
    - OBL for cardiac implant
    - Emergency evacuation device
    - Wound treatment device
    - Malariaand TB kit
    - Electro opto medical product
- National regulatory approval for
    - Import of Cardiac implants
    - Import of PTCA kit
    - Import of Haemodialysis catheter and kit
    - Import of Automated injectors
    - Import of Orthopeadic implants
    - Import of RDT
    - Import ofcancer test kit
    - Import of facial implant
    - Manufacturing drug-device combination product
    - Manufacturing orthopedic implants
    - Manufacturing ophthalmic implants
    - Manufacturing PTCA kit
    - Second brand approval for cardiac implant
    - Device addition for cardiac implant
- State regulatory approval for plan layout of
    - Medical gas filling facility
    - Orthopedic implants
    - Cardiac accessories
    - Wound dressing disposables
    - PTCA kit
- Export certificate of Ophthalmic disposables
- Gap analysis of In vitro diagnostic device
- Gap analysis of drug-device combination product
- Anvisa pre-audit for drug-device combination product
- Successful interaction with USFDA for cardiac implant PMA

Clientele catered:

- India
- Brazil
- Iran
- Pakistan
- Bangladesh
- Sri Lanka
- Vietnam
- South Africa
- EU for CE marking
- USA
- Russia
- Germany

Visits made to:

- China
- Singapore
- Mauritius
- Nepal
- U.K.
- Germany
- France
- Austria
- Switzerland
- Italy

Training undergone:

- Resomer's application in biomedical device & pharmaceutical industries (Organised by Evonik at Mumbai in June 2011)
- Medical Device regulation of India (organised by CDSCO – Indian national regulatory authority at Ahmedabad in March 2011)
- Good Laboratory Practices (Organised by CII Institute of Quality at Hyderabad in January 2011)
- Quality control and testing of plastics (Organised by CIPET Central Institute of Plastics Engineering and Technology at Ahmedabad in Sept 2010)
- Approach to stability testing (Organised by Alliance India at Mumbai in August 2009)
- ISO 14971:2007 (Organised by CE certification body DNV at Ahmedabad in August 2008)
- Manufacturing and testing of PTCA catheters (organised by Heinz Schade at Stuttgart Germany in June 2008)
- Operation and calibration of microbalance (organised by Mettler Toledo at Ahmedabad in May 2008)
- Testing and quality control of medical disposables and its raw material (organised by MDMA Medical Disposables Manufacturers' Association at Ahmedabad in May 2008)
- Intellectual property right (organised by NIIPM National Institute of Intellectual Property Management at Nagpur in April 2008)

- Internal auditor on quality management system as per ISO 9001:2008 (organised by CE certification body DNV at Ahmedabad in April 2008)
- Good Manufacturing Practices (organised by CALGS Centre for Active Learning, Guidance and Solutions at Udaipur in January 2008)
- Nuts and bolts of patent ((organised by GITCO Gujarat Industrial and Technical Consultancy Organisation Ltd. at Ahmedabad in 2004)
- Workplace education (organised by Canada India Institute-Industry Linkage Project at Ahmedabad in September 2004)
- Entrepreneurship Development (organised by Govt of India's Small Industry Development Organisation at Ahmedabad in 1994-1995)