PLAN OF WORK & RESEARCH METHODOLOGY

1. Comparison of Quality Risk Management methods for Qualitative & Quantitative analysis.

2. Various types of risks to be identified considering each activity or each step of Active Pharmaceutical Ingredient from manufacturing upto receipt at its destination.

   a. Selection and procurement of Drug - Mebendazole

   b. Indentify Risk associated with manufacturing process of Drug.

   c. Characterization of Drug

   d. Risk associated with Quality Analysis of Drug

      ➢ Residual Solvents
      ➢ Impurity Profile

   e. Effect of temperature & moisture across the time interval

   f. Identify Risk associated with manufacturing of the product upto shipment of product to its destination.

3. Case studies of Formulation & API Industries to relate different Risks & its management using ICH guideline & put focus on Regulatory part which is not yet mentioned in the guidelines.

   a. Collection of Secondary data: industry Examples from Journals, official websites.

   b. Discussion with experts sharing the knowledge reporting experience with supporting evidences.