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149.728.4596  
Shadi Bakhtiari  
QA Associate at Olympus Biotech Corporation  
White River Junction VT - Email me on Indeed: indeed.com/r/Shadi-Bakhtiari/1fbb8c28b7d7fb03  
Seeking a full-time Quality Assurance or Compliance Auditor position within the Biotechnology or Pharmaceutical industry where my technical knowledge and experience could contribute to advancement of quality product.  
WORK EXPERIENCE  
QA Associate  
Olympus Biotech Corporation - West Lebanon NH - March 2004 to Present  
\* As a certified lead auditor perform supplier and internal audits and provide audit reports to management  
\* Review and approve audit responses and corrective actions  
\* Participate and assist during regulatory inspections (FDA/EMA/GMED/TGA)  
\* As a CAPA Specialist facilitate problem solving and investigation of issues; ensure effective and timely communication of status to involved parties evaluate root cause/corrective action and perform effectiveness checks on the implemented actions  
\* Evaluate and approve change controls and update product market disposition accordingly \* Review regulatory submissions associated with change controls  
\* Review and approve validations for methods processes systems and equipment  
\* Perform comprehensive review and assessment of data for product release  
\* Provide quality assurance support for primary customers including incoming material testing validation manufacturing sales and pharmacovigilance  
\* Perform product risk assessment through evaluation of applicable quality systems to ensure risks associated with product and patient safety are continuously evaluated  
\* Use operational excellence and lean manufacturing principles to improve and enhance processes increase productivity and reduce cost  
\* Author and/or update standard operating procedures as needed  
\* Support management with compliance initiatives and quality system projects including Annual Product Review  
QC Analyst  
Olympus Biotech Corporation - West Lebanon NH - April 2003 to March 2004  
Supported functions of chemistry and microbiology laboratories. Performed environmental monitoring sterility bioburden and endotoxin assays for in-process and finished products. Prepared trend reports for Annual Product Review.  
Quality Control Chemist  
Abbott Laboratories - North Chicago IL - November 2002 to March 2003  
Performed physical and chemical analysis of bulk drug products according to USP/NF and standard monographs. Used HPLC MS IR and FTIR for detection and analysis.  
Associate Scientist  
Abbott Laboratories - North Chicago IL - April 2001 to November 2002  
Conducted Erythromycin strain development and screening assays. Analyzed secondary metabolite production using HPLC TLC and FTIR methods. Performed physical and chemical mutagenesis of S.  
   
erythreae for strain improvement and assisted in developing analytical assays for identification of efficient strains. Conducted safety audits and provided safety training for the department.  
Product Specialist  
Abbott Laboratories - Abbott Park IL - May 1995 to April 2001  
Coordinated scheduling activities and interacted with Planning Production Activity Control and Quality Assurance business units for timely release of product. Performed manufacturing and testing activities for STD/ RSV business team within the Diagnostic Division. Provided testing and manufacturing training to business team personnel. Assisted with identifying cost reduction and improvement opportunities. Performed periodic internal GMP and Safety audits and followed up on corrective actions. Performed peer review of testing and manufacturing records. Performed enzyme immunoassay small-scale manufacturing protein purification antibody conjugation and microparticle coating. Investigated deviations implemented corrective actions and initiated electronic document change. Developed and implemented procedures for control of documents and records for business teams within the Diagnostic division.  
Quality Support Specialist  
Abbott Laboratories - Abbott Park IL - March 1994 to May 1995  
Coordinated and communicated testing activities for Matrix/Allergy and Hepatitis C business teams in support of product release. Performed in-process and final release testing of finished product. Coordinated calibration schedules. Assisted in troubleshooting used problem solving and root cause analysis tools.  
Analytical Quality Assurance Technician  
Abbott Laboratories - Abbott Park IL - July 1992 to March 1994  
Performed microbiological testing of in-process and finished products. Monitored air and surface bioburden of manufacturing areas. Maintained microbial stock cultures and performed growth promotion assays. Assisted with operational qualification of gas chromatography system (MIDI) for microbial identification by fatty acid analysis. Performed microbial sensitivity studies. Trained laboratory personnel on assays. Updated testing and instrument work instructions.  
Quality Control Microbiologist/Chemist  
Blistex Inc - Oak Brook IL - October 1990 to July 1992  
Performed bioburden testing of in-process and finished products. Conducted antimicrobial preservative effectiveness and antibiotic assay studies. Prepared media maintained microbial stock cultures and performed growth promotion assays. Assisted with operational qualification of the Microbiology lab autoclave. Performed stability testing of product (hand creams and lip moisturizers). Used HPLC GC IR and UV Spectrophotometer for analysis.  
Quality Assurance Coordinator  
Smith & Nephew Solopak Laboratory - Franklin Park IL - September 1989 to October 1990  
Coordinated weekly responsibilities of QC Inspection team members and trained personnel on standard operating procedures. Approved document changes. Ensured all manufacturing and testing components drug product containers enclosures packaging materials and labels met stated specifications. As a team leader assisted in performance evaluations of QC Inspection personnel.  
Quality Control Microbiologist  
Smith & Nephew Solopak Laboratory - Franklin Park IL - June 1987 to September 1989  
Performed sterility and endotoxin testing of parentheral drug products and water. Monitored surface and air bioburden of clean rooms. Performed sterility testing of finished product. Identified microbial contaminants by biochemical assays. Assisted with operational qualification of Steritest unit. Trained laboratory personnel.  
EDUCATION  
Bachelors of Science  
Western Illinois University - Macomb IL December 1983  
ADDITIONAL INFORMATION  
QUALIFICATIONS  
An active contributor with strong work ethics. Detail oriented adaptable and a team player with excellent problem solving communication and negotiation skills. Highly organized and able to manage multiple projects. Experienced in applying quality management systems within operations and enforcing compliance with company policies and applicable industry regulations. Strong knowledge of US and international regulations pertaining to product complaints and adverse event investigations and reporting related to medical devices [...] [...] European MDD). Experienced in performing internal and supplier audits. Extensive experience in performing investigations root cause analysis CAPA and evaluating CAPA effectiveness change controls and complaints.