

Himanshu Solanki

ASQ Six Sigma Black Belt Certified

Denver, CO Email: solanki.himanshu@gmail.com Cell: (716) 548 – 3119

TECHNICAL SKILLS	<ul style="list-style-type: none"> • Root Cause Analysis • URS • AutoCAD • Control charts • Value Stream Mapping • Non-Conformances • Six Sigma, Lean • Investigations/Complaints • GxP, GMP, GAMP • Minitab, iGrafx, Visio • CAPA, Change Controls/ECN • Validation / SAT, IQ, OQ, PQ • SOPs, Batch Records, Logbook • Trackwise, BPCS • Injectables, Pharmaceuticals, Medical Device
EXPERIENCE	<p>KBI Biopharma Sep 2020 – Present <i>Specialist - Technical Writer</i></p> <ul style="list-style-type: none"> • Performing manufacturing investigations, problem solving, root cause analysis, and implementing process improvements, CAPAs, Change Controls, and Safety Improvements. • Assist with inspection preparation activities, project coordination, continuous improvement efforts to improve process robustness and efficiency and other related Technical Operations tasks. <p>American Regent Inc (Daiichi Sankyo Group Company) Nov 2016 – Sep 2020 <i>Inspection/Packaging Engineer</i></p> <ul style="list-style-type: none"> • Responsible for upgrading two packaging lines (worth \$3 million) which included creating business case, URS, MSA, equipment procurement, installation, testing, validation, Change Control, SOPs, training operators/technicians; project reduced downtime by about 22%. • Improved production line output by reducing the reject rate for multiple products, for e.g., from 24% to 6%, 4% to 0.5%, 6% to 1.2%. • Increased productivity by about 16% and provided additional space for production process by optimizing space requirement and equipment repositioning/decommissioning • Reduced changeover time by about 15% utilizing SMED • Owned root cause investigations (non-conformances), customer complaints, identify and eliminate repetitious machine failures, troubleshoot equipment and process issues under change control, and develop/implement corrective actions (CAPAs) • Responsible for setup, maintenance, troubleshooting and vision system of all Inspection and Packaging equipment including labelers, tray packers, cartoner, Eisai, Nikka and Wilco. • Process owner for particulate inspection machines, container integrity machines and packaging machines • Create, update and approve URS, change controls, Validation Protocols (SAT, IQ, OQ, PQ), knapp study reports, Operation and Maintenance Manuals, SOPs, etc. • Performed responsibilities of a System Administrator for 21 CFR Part 11 compliant equipment, and established CFR Part 11 and GxP environment in the manufacturing area • Assist APA (Aseptic Processing Area), Formulation, Filling and Glass Washroom equipment maintenance and repair as needed • Liaise closely with all levels of Production, Engineering, NPD, Validation and QA providing clear information where necessary • Support and maintain the Serialization/Track & Trace solutions; address the issues identified by EHS <p>American Regent Inc (Daiichi Sankyo Group Company) Nov 2015 – Nov 2016 <i>Quality Engineer</i></p> <ul style="list-style-type: none"> • Investigated complaints and performed root cause/corrective actions analysis. • Worked closely with manufacturing personnel in all areas involved in control of product quality. • Generated and/or executed on product and engineering change notices and update ERP system to track changes and ensure product integrity

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- Communicated with development, project management, and customer stakeholders where necessary
- Managed the execution of process validation activities including designing protocols and studies, evaluating process and assay data, investigating protocol deviations and acceptance criteria failures, and compiling final summary reports.

Zimmer Biomet

Apr 2015 – Nov 2015

Quality Engineer (Contractor)

- Continuously improve and develop processes for CAPA and NCR ensuring the processes and contents are in compliance with both relevant regulatory and internal requirements
- Conduct, perform, and review investigations for non-conformances within respective area. Able to apply six sigma problem solving tools and methods to assist investigation teams
- Coordinate the writing and updating of control plans, FMEAs, inspection check sheets, reports, and standard operating procedures
- Validated test method using Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
- Documented Test Method Validation Protocol, Test Method Validation and Test Method

iTech US Inc.

Dec 2013 – Apr 2015

Systems Analyst (Contractor)

- Document As-Is, To-Be process flows and SIPOCs as part of \$50M Brokerage Platform Conversion project; maintains Enterprise Library/Repository
- Active participation in the work stream sessions with business to understand gaps between proposed design and document To-Be processes; provide process engineering expertise to make sure the To-Be processes are designed in the most efficient manner

iWorks

Dec 2012 – Dec 2013

Process Engineer (Contractor)

- Analyzed the Federal Housing Administration (FHA) mortgage policy making process using Six Sigma and developed proposal to automate the SharePoint business process
- Used SIPOC, Cause-and-Effect Diagram, RACI and other associated tools as part of Business Process Reengineering (BPR)

SMS Siemag India Pvt. Ltd, India

Jul 2008 – May 2010

Design Engineer

- Created and validated AutoCAD mechanical Engineering Drawings of steel making plants layouts, machines and piping & instrumentation design (P&ID) as per ASME and ANSI
- Prepared Bill of Materials (BOM) and Operation & Maintenance (O&M) manuals
- Created technical specifications for machines, steel loading cars used in the plants

EDUCATION

M.S. in Industrial & Systems Engineering
State University of New York at Buffalo
May 2012

Jamia Millia Islamia, India
B.S. in Mechanical Engineering
May 2008

Himanshu Solanki

- Denver, CO, USA

Contact Information

- solanki.himanshu@gmail.com (Preferred)
- 7165483119 (Preferred)

Work History

Total Work Experience: 6 years

- **quality engineer | biomet 3i**
Jan 01, 2015 - Jan 01, 2014 | San Antonio TX United States

Skills

- **controls** | 4yrs | 2020
- **inspection** | 3yrs | 2020
- **manufacturing** | 3yrs | 2020
- **problem solving** | 2yrs | 2020
- **layout** | 5yrs | 2019
- **compliance** | 4yrs | 2019
- **investigation** | 4yrs | 2019
- **iq** | 4yrs | 2019
- **cost reduction** | 3yrs | 2019
- **ehs** | 3yrs | 2019
- **production engineering** | 3yrs | 2019
- **packaging engineering** | 3yrs | 2019
- **urs** | 3yrs | 2019
- **qa** | 3yrs | 2016
- **reporting** | 3yrs | 2016
- **corrective and preventive action** | 3yrs | 2016
- **verification and validation** | 3yrs | 2016
- **business requirements** | 2yrs | 2016
- **installation** | 2yrs | 2016

- **oq** | 2yrs | 2016
- **pq** | 2yrs | 2016
- **consulting** | 2yrs | 2015
- **six sigma** | 2yrs | 2015
- **process engineering** | 2014
- **validation** | 2014
- **autocad** | 2014
- **flash** | 2014
- **spss** | 2014
- **spc** | 2014
- **bill of materials** | 2yrs | 2010
- **specification** | 2yrs | 2010
- **engineering**
- **packaging**

Work Preferences

- Likely to Switch: Possibly
- Willing to Relocate: Yes
- Travel Preference: Up to 50%
- Work Authorization:
 - US
- Work Documents:
 - Have H1
- Security Clearance: No
- Third Party: Yes
- Employment Type:
 - Contract - W2
 - Contract to Hire - Independent
 - Full-time
 - Contract to Hire - W2
 - Contract - Independent

Profile Sources

- Dice:
<https://www.dice.com/employer/talent/profile/d85a17a0715c6449e9216aed2b675dc426486184>