

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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EDUCATION	<p>M.S. in Industrial & Systems Engineering State University of New York at Buffalo May 2012</p> <p>Jamia Millia Islamia, India B.S. in Mechanical Engineering May 2008</p>

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>