HIMANSHU SHARMA

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To work for an organization which gives me ample opportunity to explore and showcase my capabilities, skills and in turn whatever I do, I ensure that I do it in the best possible, effective and an ethical manner.

Willing to relocate: Anywhere

# Skills

Proficient in pharmaceutical applications/software: PAS-X, SAP, GQCLIMS, BIO-DISCOVERANT, ORACLE ERP, MATLAB, PRISM-GraphPad

ARGUS V8, MedDRA coding, Medical writing, Clinical trial processes, c-GMP, c-GCP/c-GLP, BMR, JDE, SHE.

# Work Experience

**Bio-Processing Engineer**

AstraZeneca | Frederick | Maryland, December 2018 – present

* Implementation of **upstream** / **downstream** / central services processing equipment according to established SOPs.
* This equipment includes but is not limited to **bioreactors** (Harvesting virus, cell culture), Buffer/media preparation, chromatography skids (Column packaging), **Ultrafiltration/Diafiltration skids**, autoclaves, washers, and product hold tanks. Recipe via **MPR** and **EBR** driven **CIP/SIP** of tanks and transfer lines. Installation of bio-filters, single use filters and integrity testing of filters.
* pH/conductivity meters calibration and routine checks, **spectrophotometer (SoloVPE)**, **BOM set-up**. Sterile connections/disconnections for product transfer from tanks to allegro bag, Allegro bag/cart/tote set-up, Mag-mixers
* **Inventory management** (WIP, BOM), **Enterprise Asset Management using ORACLE ERP**.
* Participated in internal audits and **FDA audits**. Post-audit **CAPA** implementation.

**Chemistry Lecturer**

Lilongwe Private school |Malawi, August 2014 to November 2018

**Pharmacovigilance Associate**

WIPRO | New Delhi, January 2010 to July 2014

* To perform Individual Case Safety Report (ICSR) and to close processed ICSRs on Oracle Argus Safety database.
* **Database entry**/case processing of ADR and SAE in the internal safety database (**Argus ver.8.0**) within various tabs (i.e. General, patient, product and events tab). Clinical trial cases
* **MedDRA coding** and structured abstract/**narrative writing**, Seriousness, expectedness and **causality assessment** in Argus.
* In-depth knowledge and understanding of **clinical trial processes** and **international regulatory requirements** (US-FDA, EUDRAvigilance).

**Formulation Scientist**

MENTHOLATUM | Scotland, October September 2006 to December 2009

* Manufacturing of topical creams, emulsions, gels and ointments as per SOP under **cGMP** and UKMHRA.
* Maintenance of batch records, JDE’s, requisition records and SHE records.
* Update all document as per UKMHRA standards & **c-GMP, c-GLP/c-GCP**.
* Calibration of equipment used in formulation (i.e. mixers, homogenizers, filters).
* Worked as process engineer for new product R&D, process development, process scale-up and technology transfer.

## Production Pharmacist

Wings Pharmaceuticals | Delhi, Delhi January 2003 to July 2005

* Worked in the In Process Quality Control (IPQC) under **WHO- cGMP/c-GCP** guidelines for the testing of pharmaceuticals under production, taking samples from the running machines and documenting the results.
* Prepared SOPs of batch production of tablets, capsules, ointments, syrups.
* Also supervised the other departments of Pharmaceutical production, such as Granulation section, packaging.

Education

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## Master's in Immunopharmacology

UNIVERSITY OF STRATHCLYDE - Glasgow, SCOTLAND

August 2005 to September 2006

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## Bachelor's in PHARMACY

S. B. S (P.G) I. B. M. S - Dehradun, Uttarakhand

August 1998 to July 2002

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# Assessments

## Written Communication — Proficient

Jan 2019

View my full results at: <https://share.indeedassessments.com/share_assignment/673mv40o6anljgvn>

## Problem Solving — Familiar

Jan 2019

View my full results at: <https://share.indeedassessments.com/share_assignment/9yy3duzz7-nz8jqq>

## Organizational Skills — Proficient

Jan 2019

View my full results at: <https://share.indeedassessments.com/share_assignment/ku6hscfuczitznyl>

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