

# Amar Savalia

## Downstream cGMP Waste, and Sanitization Process Engineer - Sanofi Pasteur

Yardley, PA - Email me on Indeed: [indeed.com/r/Amar-Savalia/577280ddfdb7226](https://www.indeed.com/r/Amar-Savalia/577280ddfdb7226)

Willing to relocate

Authorized to work in the US for any employer

### WORK EXPERIENCE

#### Downstream cGMP Process, Waste, and Sanitization Process Engineer

Sanofi Pasteur - Swiftwater, PA - September 2014 to Present

- Experience in implementing Process Development, reviewing and coordinating technical equipment specification for cGMP Influenza vaccine manufacturing facility throughout the following phases: Feasibility, Preliminary Design, Basic Design/BOD, and Detailed Design.
- Led the harmonization effort for all downstream equipment to meet the needs for both distinct Fluzone (US) and Vaxigrip (France, Mexico) processes of the Influenza vaccine manufacturing process.
- Global Leader for Sanitization and Waste processing for Sanofi French, Mexican, and US sites for the following pieces of equipment: egg waste dehydrator transfer/ preprocessing system, egg waste dehydrator system, egg waste off gas treatment system, liquid biowaste kill system, liquid industrial waste system, sonicator systems, and egg embryo harvester parts washer.
- System owner for the following pieces of equipment: GMP Autoclaves, decontamination autoclaves, GMP parts washer, tray washer, cart washer.
- System owner for Tangential Flow Filtration Membrane, disk stack centrifuge, ultra centrifuge (40 K RPM), continuous table top centrifuge and rest of post harvesting system downstream vaccine purification process during BOD phase of the project.

#### Bioprocessing and Fermentation Engineer

Cobalt Technologies, Department of Fermentation - Mountain View, CA - January 2011 to July 2014

- Experience in Process Development in fermentation under anaerobic and aerobic setting using *C. pasteurianum* and *E. coli*.
- Committed to implementing new fermentation processes for custom built immobilized packed bed bioreactor systems and other bioreactor system using Static Batch, Fed Batch, and Chemostat.
- Highly capable in mammalian and microbial cell culture inoculum preparation and sterile transfer into reactors from 500mL, 1L, 5L, 10L, all the way up to 10000L fermenters.
- Avid experience in data interpretation of fermentation off gas, chemical and solvent production.
- In charge of commissioning HTST/UHT machine used for media sterilization used for scale up fermentation and process metrics confirmation between large and bench scale fermentors.
- Achieved highest solvent titer at lab scale via process, media and reactor configuration optimization.

- Prepared technical SOPs for use of equipment, reactor setup, and other technical processes.
- Responsible for delegating tasks and allocating them amongst team members.
- Experience in establishing mammalian and bacterial cells seed progeny lines for reactor inoculation.
- Well versed in aseptic techniques to ensure most efficient and contamination free fermentation.
- Helped pioneer profitable non-sterile fermentation at Research and Development scale.
- Lead for company safety committee to ensure a safe working environment for all workers overseeing safe practices and procedure were followed.

### **Cancer and Tumor Researcher**

Moore's Cancer Institute - La Jolla, CA - May 2010 to December 2010

- Conducting research on using Nanoparticles embedded with specific human peptides.
- Developing nanoparticles with the goal of eliciting or preventing a specific immune response to hinder tumor growth and metastasis of tumor into new tissue.
- Responsible for identifying pathways and cytokines produced.
- Ran SDS- Page, Western Blot and Gel Electrophoresis to confirm correct insertion of protein peptides in nanoparticles.
- Performed bacterial and mammalian cell culture growing analysis in bioreactor environments
- Responsible for weekly synthesis of nanoparticles and embedding them with Human Peptide 91.
- Performed ELISA for Immortal cell detection to help culture of HeLa (cervical cancer cells lines) for research.

### **Analytical Scientist**

General Atomics - San Diego, CA - October 2009 to October 2010

- Conducted research for analytical laboratory for Algae Research running and recording elemental and toxin content screening, Total Carbon/ Nitrogen screening, and running chlorophyll content including all the preparatory work for each assay.
- Experience in Gas Chromatography and Inductively Coupled Plasma trace metal analysis on samples.
- Operated and maintained equipment for fluid extraction/separation of flocculent and harvesting of algae biomass.

## **EDUCATION**

### **Bachelor of Science in Bioengineering**

University of California - San Diego, CA

## **ADDITIONAL INFORMATION**

### **AREAS OF EXPERTISE**

- Expert in process/equipment engineering for Influenza Vaccine manufacturing cGMP process
- Avid in technical summary in preparing and reviewing Process Flow Diagrams (PFD), Piping and Instrument Diagrams (P&ID), User Required Specification (URS), Technical Specifications, Functional Required Specification (FRS), and Standard Operating Procedures (SOP).
- Practiced in Cellulosic based Fermentation in sterile aerobic and anaerobic setups
- Have grown various microorganisms for the production of chemicals used to make industrial solvents, pharmaceuticals and other fermentation related products.

- Ability to thoroughly perform CIP and SIP for closed loop vessel decontamination and cleaning.
- Meticulously implemented cGMP protocols, guidelines, and maintained cGMP lab notebook.

#### TECHNICAL SKILLS

- Experience in culturing of proprietary forms of the following organisms: recombinant E. coli, C. pasteurianum, algae forms and mammalian cells including immortalized (human) HeLa cells.
- Well practiced in reactor inoculation including starting seed train from suspended cell stocks
- Proficient in the following lab techniques: titration, centrifuging, micro pipetting, pH regulation, and complex media formulation using stringent aseptic technique.
- Performed live measurements of engineering process variables using SCADA systems information to continually update operation metrics to ensure quality control in product formation.
- Aptitude in performing the following lab assays: ELISA, SDS PAGE, protein extraction/purification, recombinant DNA, DNA restriction digest and cDNA synthesis using appropriate enzymes.
- Comprehensive knowledge of common bioreactor contaminants and identification including growth tracking within bioreactors used to grow bacteria, mammalian cells or algae species.
- Ability to perform various biomass separations techniques to isolate/extract product compounds.
- Proficiency in handling hazardous chemicals including safe use, storage and proper compatibilities.