SANJEEV K. GUPTA, PhD

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Citizenship: Indian

SUMMARY

- Biotech professional with over **19 years** of industrial experience in Biosimilar development
- Developed and contributed for over **12 recombinant molecules**, of which **08 Biosimilar products** have already been launched in India and rest are in the developmental or clinical phase
- Established a new state of the art **Biotech R&D facility** for the development of mAb Biosimilars and also actively involved in **establishing single use Bio-manufacturing facility** for Biosimilar commercial launch
- Research has been presented in various **national and international conferences** (IBC, Terrapin, Cphi, IMAPAC, Biopharma etc.)
- **Published** several research articles, book chapters, magazines and patent in lieu of the Biosimilar development

CORE COMPETENCIES

- Biosimilar product development (mAb and Non-mAb proteins)
- Research and Development **(R&D) facility establishment** (End to end)
- Project management-coordinating with various research groups involved in Biosimilar product development
- Regulatory submission and approval for various activities
- Technology evaluation and In-licensing
- Technology Transfer and reproduction

MAJOR ACHIEVEMENTS

- Recombinant Products **(8 Biosimilars)** launched in India
- Development and launch of **world's first** Biosimilar molecules **(03)** in India
- Development of indigenous Cell line, Process, Bio-assay and Analytical capabilities
- In-house cell line and process with **high titer** (mAb) and quality matching with Innovator product (5-50L scale)
- Recombinant product development from "**Clone to Clinic"**
- **Antibody Library generation** for the identification of novel therapeutic targets

PROFESSIONAL BACKGROUND

Ipca Laboratories Ltd., Mumbai, India **2013 to Present**
Sr. General Manager and Head-Advanced Biotech Lab (Biosimilar R&D)

- **Head**-Advanced Biotech Lab **(R&D)** for Biosimilar development
- Directly reporting to Managing directors and President
- Decision making for Biosimilar **R&D and manufacturing** activities
- Handling team of over **40 peoples and 8 different** functions
- In-house **clone and process development** up to **50L scale (Single-use)**
- **Pre-clinical studies** and tech transfer to manufacturing
- People and project management for Mol Bio, Cell Line Dev, Upstream, Downstream, Analytical, Bioassay, Formulation/Stability and RA/QA in lieu of Biosimilar development
- Establishment of single-use multi-product Bio-manufacturing facility (DS & DP)
- Technology evaluation and In-licensing/tech transfer & tech reproduction of various technologies linked with Biosimilar product development

Intas Biopharmaceutical, Ahmedabad, India **2008 to 2013**
Assistant General Manager and Head-Cell Line Development

Launch of three indigenously developed world's first Biosimilar products and four other mAb and Non-mAb biosimilars

- Technology evaluation and In-licensing/tech transfer & tech reproduction of various technologies linked with Biosimilar product development (03 molecules)
- Cloning and expression of recombinant proteins in bacteria (*E.coli*) and mammalian (CHO) platforms
- High producer Stable cell line development (03 molecules)
- Upstream process development for Biosimilar products
- Project management for development and commercialization of recombinant products

Panacea Biotec Ltd., New Delhi, India **2005 to 2008**
Senior Scientist, Biopharmaceutical Research Centre

Cell line and process development for two Biosimilars

ScFv Antibody library generation in a novel expression platform

Wockhardt Research Centre, Aurangabad, India **2003 to 2005**
Scientist- Genomics Lab

Launch of indigenously developed insulin analogues in India

- Cloning and expression of recombinant proteins in bacterial and yeast platforms
- Clone screening, selection and Stable cell line generation

Zydus Research Centre, Ahmedabad, Gujarat, India **2000 to 2003**
Sr. Biotechnologist-Molecular Biology Lab

Molecular cloning and cell line/clone development for Biosimilars

EDUCATION

Ph.D., Cell Metabolic Engineering (Microbial Biotechnology) **Aug 2016**
Maharshi Dayanand University, Rohtak, HR, India
M.Sc., Applied Microbiology & Biotechnology **Jun 2000**
Dr. Hari Singh Gour University, Sagar, MP, India

AWARDS

- Qualified **GATE-2000** (Graduate Aptitude Test in Engineering) with 86.03 percentile, Ministry of Human Resource, Govt. of India.
- Diploma in "Biotechnology and Intellectual Property" from World Intellectual Property Organization (2008), **WIPO** worldwide academy, UN

NATIONAL AND INTERNATIONAL CONFERENCES

Invited Speaker (Key conferences):

- Panelist for discussion on Bio-manufacturing and regulatory approaches for Biosimilars organized by CphI, New Delhi India , 12th Dec, 2018
- Conference moderator in an international conference " Biological Manufacturing India, **Pune-India** organized by IMAPAC, Singapore (20th -21st Feb-2018)
- In an international conference "BioPharma Asia Convention-2017, **Singapore**, organized by IBC (22nd -23rd Mar-2017)
- In a national conference "Antibodies and Drug Conjugates, **Bengaluru, India** organized by SelectBio (29th -30th Sept-2016)
- Invited speaker and panelist for "Cell line development and Engineering conference", 2014, **Vienna, Austria** (10th to 13th Feb, 2014)
- Workshop trainer in "Cell line development and Engineering conference", 2013, **Vienna, Austria** (11th to 15th Feb, 2013)
- Panelist in an International Conference "Antibody Engineering & Therapeutic Asia 2010", **Sanghai, China** (11th-13th Nov, 2010)

PATENTS AND PEER-REVIEWED PUBLICATIONS

Patent

1. Patent publication: PCT-**Patent no. WO 2012/077128 A1 (**"A Novel Cell Line Development strategy for production of recombinant proteins")

Book Chapters

1. **Delve Publishing, 2018:** Antibody Drug Conjugate for Targeted Therapy: A New Avenue"
2. **Delve Publishing, 2018: "**Developing Nucleic Acid Bio-sensors and Its Therapeutic Relevance".
3. **Elsevier, 2018:** "Effectual bioprocess development for protein production using Cell line engineering" (Under printing).
4. **Wiley-VCH, Oct, 2017**: **"**Upstream Continuous Process Development.

5. **Wiley-VCH, Jan, 2015**:"Implementation of CQA(Critical Quality attribute) based approach for development of Biosimilars"

Research Articles

1. **Gupta SK,** Salvi D. (2019). Next wave of Bio-therapy. Cutting Edge, Page 66 *(Magazine).*
2. Singh S., **Gupta SK,** Kumar A. **(2018).** Some thoughts on how to secure sustainable future in Biosimilar world*. Pharma Bio World (Magazine) (Page 8-16).*
3. Dangi AK, Sinha R, Dwivedi S, **Gupta SK,** Shukla P. **(2018)**. Cell line techniques and gene editing tools for antibody production: A review. *Frontier in pharmacology.*9:630. doi:10.3389/fpharm.2018.00360.
4. **Gupta SK,** Shukla P. **(2018).** Glycosylation control technologies for recombinant therapeutic proteins. *Applied Microbiology and Biotechnology.* https://doi.org/10.1007/s00253-018-9430-6 **(IF 3.34)**
5. Raut S, **Gupta SK. (2017).** "Bioassay development for mAb characterization"-a critical requirement for biosimilar. *Cutting Edge (Magazine).*
6. **Gupta SK**, Shukla P.**(2017)**. Sophisticated Cloning, Fermentation, and Purification Technologies for an Enhanced Therapeutic Protein Production: A Review. *Frontiers in Pharmacology.* Doi: 10.3389/fphar.2017.00419 **(IF4.4).**
7. **Gupta SK**, Sharma A, Kushwaha H, Shukla P. (**2017**). Over-expression of a Codon Optimized Yeast Cytosolic Pyruvate Carboxylase (PYC2) in CHO Cells for an Augmented Lactate Metabolism. *Frontiers in Pharmacology.* Doi: 10.3389/fphar.2017.00463 **(IF4.4).**
8. **Gupta SK,** Srivastava SK, Sharma A, Nalage VHH,Salvi D, Kushwaha H, Chitnis NB, Shukla P.**(2017)**. Metabolic engineering of CHO cells for the development of a robust protein production platform. *PLOS ONE*, 1-23. doi.org/10.1371/journal.pone.0181455. **(IF2.806)**
9. Sharma MK, Raikar S, Srivastava S, **Gupta SK. (2017).** Examining Single-Use Harvest Clarification Options.**A** Case Study Comparing Depth-Filter Turbidities and Recoveries. *BioProcess International*.15(2); 40-47**.**
10. Chaudhari PS, Nath R, **Gupta SK.(2017).** Opportunities and Challenges in Biosimilar Development. *BioProcess International*.15(5); 24-33**.**
11. Dwivedi S, **Gupta SK.(2016)**. CRISPR/Cas9: A prodigious traveler from bacterial to human genome. *Cutting Edge (Magazine)*
12. **Gupta SK**, Shukla P.**(2016)**. Bacterial platform technology for recombinant antibody fragment production: A review. *Critical Reviews in Microbiology.* DOI:10.3109/ 1040841X.2016.1150959 **(IF 8.192)**.
13. **Gupta SK**, Shukla P. **(2016)**. Gene editing for cell engineering: trends and applications. *Critical Reviews in Biotechnology*. Manuscript ID BBTN-2015-0157.R1. DOI: 10.1080/07388551.2016.1214557 **(IF 7.510)**.
14. **Gupta SK**, Shukla P. **(2015)**. Advanced technologies for improved expression of recombinant proteins in bacteria: Perspectives and applications. *Critical Reviews in Biotechnology* 1-10. doi:10.3109/07388551.2015.1084264 **(IF 7.510)**.
15. **Gupta SK. (2015).**"Post translational Modification-an analytical approach for Biosimilars".*Cutting Edge (Magazine).*