



# Case Study 1

PARAS BIOPHARMACEUTICALS  
(BIOLOGICS CDMO)  
OULU, FINLAND



## Case Study 1

### **Successful Soluble (Fully Folded) Expression & Production of Cytokine for USA Client for TOX Studies:**

The Paras Biopharmaceuticals team took a major challenge in 2018 / 2019 to develop & carry out efficient production of fully-folded biologically active product in E. coli. Product requirements of USA client was significant, as extensive Tox studies were planned in 2020 / 2021. The Paras Biopharmaceuticals team produced and supplied bulk / pre-formulated bulk (in highest quality) to USA biopharma company. The project was extended, and multiple batches of biologics were produced and delivered.





# Case Study 2

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## Case Study 2

### **Development of Efficient Bioproduction Production Process for European Cell & Gene Therapy company:**

The Paras Biopharmaceuticals team was assigned to carry out a significant Bioprocess Enzyme to be developed and scaled up to 750 L scale with downstream Purification. The European client audited Paras Biopharmaceuticals scale-up production facility in Finland. Paras Biopharmaceuticals' team successfully produced multiple batches at 750 L scale and delivered to European client.





# Case Study 3

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## Case Study 3

### **Challenging Fc-Fusion Protein (for scale-up production in E. coli):**

The challenge was to successfully express, develop a non-glycosylated Fc-Fusion in E. coli. The product required non-glycosylated form because of its applications in requisite therapeutic areas. The Paras Biopharmaceuticals team has long history and strong experience of working on therapeutic Fab, fragment, DARPINs and scFv formats.

The Paras Biopharmaceuticals team took up the challenge and successfully carried out Fc-Fusion in E. coli. The project was scale-up with strict quality control (QTPP) and quality requirements of matching CE-SDS, charge heterogeneity, purity with reference product.





## Case Study 4

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### Case Study 4

#### **Successful Implementation of Paras Biopharmaceuticals Multiple Technologies (Biomultifold, NobleClev & Cytofold StructQuant) in Difficult to Express Biologics:**

The project challenge was significant. It was a rare & orphan disease product. USA client made efforts to develop the extremely hydrophobic biologic in USA, but the product yield was significantly low and commercially non-viable. The Paras Biopharmaceuticals team took over the challenge and successfully developed authentic biologics, overcame process-related challenges and significantly increased productivity. Combination of Paras Biopharmaceuticals' Biomultifold, NobleClev and Cytofold StructQuant technologies were successfully implemented together.



Paras Biopharmaceuticals' Unique Technologies, located in Oulu, Finland





# Case Study 5

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## Case Study 5

### **Development of High Productive Production Process of a Biosimilar Candidate for a European / USA Client:**

European / USA client had urgent requirements. The Pharma company was looking for Paras Biopharmaceuticals to take up “Development of Biosimilar candidate” as a ‘turnkey’ project and scale-up production process & handover the entire development, manufacturing batch records, production strain (clone) and documentation.

The Paras Biopharmaceuticals team carried out the entire development for gene synthesis, expression strain development, scale-up (upstream development) and downstream purification, analytical method development and characterization in a record 8 months, and project was successfully delivered.

