



# ATMP and Biologics Manufacturing

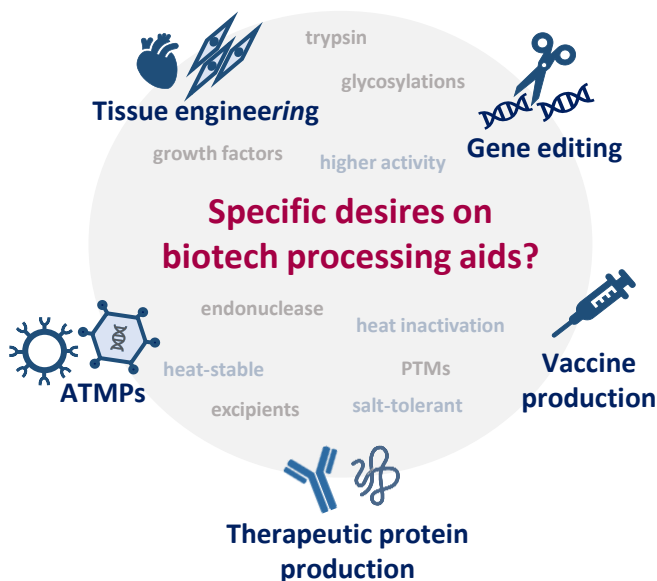
## The underestimated role of Accessory Biotech Products

c-LEcta provides production process innovation through unique enzymes and other accessory proteins, that have been engineered to cope with very specific requirements. We apply our unique expertise and comprehensive experience in **protein engineering**, following the principles of natural evolution, to develop and produce proteins for tomorrow's industry. Consequently, we cover the value chain from **product development, regulatory approval & registration to commercial scale production.**

**We would like to invite your experts to exclusively discuss how to improve current processing aids (enzymes and other proteins) in the manufacturing of Biopharma products**

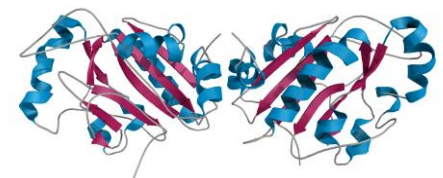
### Accessory biotech products – Key tools in Biopharma

### Track Record in Biopharma



c-LEcta already successfully established products for pharma and biopharma applications in the market that comply with regulatory standards.

Exemplary, we offer **DENARASE®** as full EU GMP grade product. DENARASE® is a genetically engineered endonuclease that is mainly used as a DNA eraser in purification processes in the scope of vaccine manufacturing or viral vector production for gene and cell therapy.



**DENARASE®**

### Proteins can be improved for:

- Better availability/quality
- Higher efficiency
- Higher stability
- Adapted pH profile
- Adapted temperature profile
- ...

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# Open Innovation for proteinaceous processing aids

In recent years research efforts were mainly directed on the development of ATMPs like gene and cell therapeutics, while accessory biotech products from shelf had to be used in the manufacturing. It may therefore be assumed that the potential for optimization of such processing aids has not been fully exploited. However, to truly innovate, Protein Engineers need the Application Experts' input. c-LEcta can offer the following:

## Outstanding Enzyme Development Platform

Enzyme engineering to enable **disruptive process technologies**



## Proprietary Microbial Production Platforms

3 high performance expression platform (*Bacillus*, *E. coli*, *Pichia*). **Unique expertise with Bacillus**, certified production plant (EXCiPACT-GMP)



## In-depth regulatory Expertise

Product approval & registration; ISO9001, EXCiPACT-GMP, **Pharma-GMP**



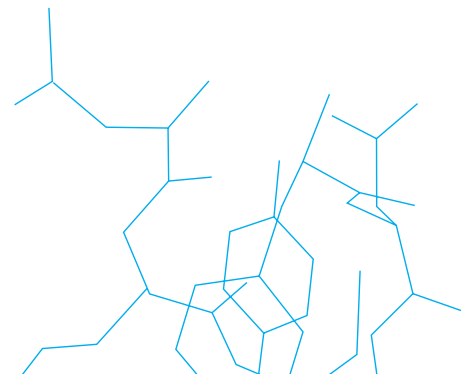
## Proven track record

Multiple processes transferred into commercial scale; established supplier for industry, routine production even under Pharma-GMP



We look forward to **align the expertise of both companies to enable true innovation in the so far neglected field of processing aids**, namely to:

- facilitate downstreaming and increasing yield
- adapt enzymes to your process conditions
- improve availability and quality of your product
- enable new modifications of therapeutic proteins or viral vectors
- support your new technologies



## Trusted partner for the Biopharma industry

With our products, such as the endonuclease DENARASE®, the DENARASE® ELISA Kit and our c-LEcta Plug & Play Biocats™, we supply over 500 customers around the world, including 7 of the TOP10 pharma companies.

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