VALIDOGEN - *Pichia pastoris* Protein Expression Excellence

**Company name:** VALIDOGEN GmbH  
(formerly known as VTU Technology)  
**Headquarter:** Raaba-Grambach, Austria  
**Founded:** 2008

**Contract Research Organization, CRO** serving  
(bio)-pharma, diagnostics, food & feed, chemical, agro  
and other industries

- Time-saving protein expression studies
- Comprehensive production strain development
- Bioprocess development
- Protein purification and DSP development
- Cell banking
- Enzyme engineering

VALIDOGEN is a leading contract research and development company located in Austria, providing services for the fast-track generation of high performance *Pichia pastoris* protein production strains and economically viable protein production processes for biopharmaceuticals and other proteins.

Judging from numerous completed and ongoing development projects, protein production processes developed in VALIDOGEN’s labs have been shown to be robust and scalable facilitating sound technology transfer and straightforward implementation in large scale production facilities.

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To date several VALIDOGEN customers have licensed and successfully scaled-up commercial production processes for the manufacture of recombinant proteins with VALIDOGEN’s Pichia system known as UNLOCK PICHIA to volumes ranging from several hundred to more than 50,000 l.

VALIDOGEN has established a broad range of tools and know-how for the generation of high performance Pichia processes. Exclusive proprietary technologies and profound experience of the VALIDOGEN team lead to competitive production processes for a wide range of recombinant proteins including:

- antibody fragments
- protein scaffolds
- fusion proteins (Fc-and albumin fusion)
- cytokines and growth factors
- hormones
- vaccine antigens
- enzymes
- allergens
- serum proteins

**UNLOCK PICHIA - broadest Pichia protein production toolbox**

VALIDOGEN’s exclusive highly approved 1st generation library of synthetic methanol-inducible PAOX1 promoter variants forms the core of the company’s cutting-edge in-house Pichia pastoris toolbox enabling high-level protein production of up to 25 g/l of secreted protein (peak productivity of 35 g/l). This library was complemented with groundbreaking and unique methanol-free 2nd generation PAOX1 promoter variants, facilitating strong expression even with just glycerol or glucose as the sole carbon source clearly outperforming conventional promoter systems. In addition to abolishing toxic and explosive methanol as a substrate, while retaining high expression levels of up to 20 g/l, major advantages of this new technology are reduced oxygen consumption and therefore significantly reduced heat production and cooling effort in bioreactor cultivation as well as a significant potential to reduce process time and cost of goods.

The versatility and effectiveness of VALIDOGEN’s Pichia system is further underlined by:

- a set of proprietary expression enhancing helper factors
- several platform strains with different genetic backgrounds
- elaborated cloning and transformation protocols
- a high-throughput microscale cultivation and screening regime
- effective bioreactor cultivation protocols

Meanwhile, the *Pichia pastoris* expression system is an established, FDA approved, safe (GRAS) and highly competitive expression system with strong secretory capacities while secreting only low amounts of endogenous proteins. Today, a large number of recombinant protein products on the market (pharma and non-pharma applications) are produced in *Pichia pastoris*.

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