04. PEPTIDE SUPPLY

Recombinant Peptide Supply
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1. Executive Summary

Phenotypeca has used its proprietary Quantitative Trait Loci (QTL) technology to create libraries of proprietary yeast strains, capable of recombinant manufacture for a variety of peptides. This is being used to manufacture and supply peptide ingredients for skincare and beauty products.

Such recombinant manufacture addresses a number of key restraints presently compromising peptide supply:

The recombinant manufacture of many peptides is not possible or is technically challenging using standard host cell chassis and gene engineering of such chassis.

Solid state synthesis struggles to make peptides containing ~30 or more amino acids at a cost feasible for the commercial needs of consumer products.

Consumers are looking for products with good sustainability credentials. Solid state synthesis requires considerable quantities of non-reusable solvents and materials, high energy usage, plus high levels of product failure and associated waste.

The standard of peptides from synthesis can be variable at large-scale production.

Solid state synthesis has limitations as to how low the costs of manufacture can go.

Such cost limitations can lead to compromises in the quantities of peptide used in final product formulations, undermining the effectiveness of such products.

Phenotypeca uses production strains optimised by QTL technology to supply low-cost, high-quality recombinant peptides from a natural, sustainable source of Saccharomyces cerevisiae (baker's yeast). This opens up the vast reservoir of larger peptides, growth factors, cytokines, and proteins that are presently not affordably accessible to the skincare and beauty industries.

2. Technical Overview

QTL Technology: QTL technology harnesses the power of evolution to develop Saccharomyces cerevisiae strains optimised for the manufacture of each protein or peptide. Phenotypeca has used the technology to create strain libraries that harness vast genetic diversity, sourced from around the world, that evolved over millions of years in diverse environments.

Iterative cycles of breeding, screening, and proprietary genetic analysis of the better-performing strains enable Phenotypeca to utilise multi-parameter optimisation to create strains tailored to the needs of each protein. As a consequence, we have created proprietary strain libraries, several of which are suited for the manufacture of peptides.

Not all peptides are suitable for recombinant manufacture; however, for your peptide of choice, the feasibility can quickly be established and verified before proceeding further.

The technical challenges associated with the recombinant manufacture of small and large peptides differ. Consequently, the solutions provided for each peptide by Phenotypeca's strains vary between small and large peptides, as do the methods of purification and recovery.

3. Commercial Engagement

Pricing of the peptides and the concentrate suitable for inclusion in final product formulation is agreed upon up front. The reference standard, purity levels and validation analytics are also agreed in advance, together with any other bespoke requirements.

In advance of formalising commercial supply, Phenotypeca uses its proprietary 2-micron plasmid to insert the gene sequence of the specific peptide into relevant strains within their libraries. This establishes the feasibility of recombinant manufacture of the specific peptide, while identifying the better-performing strains. This also clarifies the outline economics of the manufacture, allowing the terms of ongoing supply to be determined and agreed in advance.

Samples and key multi-batch analytical data for validation of the peptide are provided in advance of finalisation of the supply agreement. Demonstration of the fermentation performance using the strains to generate the target peptide can also be arranged.

Included in the supply agreement is a timetable for the delivery of the peptides, which includes an initial period for fermenter and purification scaling to the levels required for the requested

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quantities. Thereafter, an advance payment is made for the initial supply, including the quantities and a schedule for ongoing delivery of the peptide.

4. Technology Transfer of Supply Model

The strains used for peptide manufacture will be protected by patents and other IP owned by Phenotypeca. Included in the supply terms is a license to use peptides manufactured using such proprietary strains. The patents prevent competitors from using the strains or alternative strains containing the genetic alleles critical for efficient recombinant manufacture of the peptide concerned.

Exclusive licensing of a given peptide can also be provided, depending on the circumstances of the peptide and subject to appropriate terms.

Phenotypeca is developing a range of proprietary skincare peptides available for supply, each of which has carefully defined and validated skin benefits that have been identified as being desirable to consumers. Some of this portfolio is composed of recombinant versions of proteins or peptides endogenous to human skin and important for its homeostasis.

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