




TBD-BIODISCOVERY

ONE-STOP-SHOP OF FINE CHEMICALS AND API-S



TBD-Biodiscovery: WHAT WE DO

- Contract manufacturing of active pharmaceutical ingredients for generics and original drugs
 - Contract manufacturing of investigational medicinal products for clinical studies
 - Contract research in chemical synthesis/process development
 - Contract research and experience with cytotoxics
 - Analytical chemistry: method development
 - Interdisciplinary projects: chemistry and microbiology
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TBD-Biodiscovery: History

2006 - founded as a spin-off company of the University of Tartu, 2 persons

2011 - starting the commercial production of APIs

2013 - 22 persons, 10 from them are PhD

Clients: pharma and biotech all over the world





TBD-Biodiscovery: The company

- Located at Tartu Biotechnology Park
- ca 550 m² of working space in total
- R&D area
- Manufacturing area
- Reactors: 15 L, 20 L, 30 L, 50 L, 2x80 L, 100 L
- Analytics *in-house*: 3 x HPLC, GC, FTIR, UV-Vis etc
- GMP certified manufacturing area with Class D cleanroom
- Separate facility with Class B cleanroom for cytotoxics








Contract manufacturing for pharma: GMP

- 2008 - a certificate of GMP compliance to manufacture active pharmaceutical ingredients by chemical synthesis (*issued by Estonian State Agency of Medicines and corresponding to the guidelines of European Good Manufacturing Practice laid down in Directive 2003/94/EC*).
- 2011 – construction and qualification of a new class D cleanroom. First batches of active pharmaceutical ingredients are produced.
- Production of API for generic drug
- Production of API precursor for clinical trials



Contract manufacturing for pharma: GMP

- An established system of inner regulations (SOPs) and quality assurance /quality control procedures.
 - Regular self-inspections.
 - Regular GMP-compliance customer audits:
 - Last audit: June 2012 (a pharma company from Germany)
 - Audit result: successful
 - Project accepted: Oct 2012
 - Regular internal and external GMP-related training provided by specialists and authorities.
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Contract manufacturing for pharma: SCOPE

- Reactors from 15 L up to 100 L
- Operation scale: from 100 mg up to kilos.
- Biggest batch at the moment: 10 kg
- Max annual volume capacity: 300-400 kg



Contract manufacturing for pharma: TWO OPTIONS

As a customer-focused company, TBD-Biodiscovery offers two options for the customers:

- **small-scale manufacturing of niche products and products for clinical trials**

- milligrams, grams, kilos

- **commercial scale manufacturing**

- 300-400 kg per year with expansion possibilities



Contract manufacturing for pharma: how do we work

Multi-step synthesis from mg to multi-kilo level based on customer's technological process or developing the technological process for the customer:

- Literature/patent searches (including literature in Russian language)
- Route scouting
- Feasibility studies
- Process development
- Upscaling
- Preparation of validation and pilot batches
- DMF compilation
- Technology transfer up to commercial production.



Contract research in chemical synthesis

- Providing R&D services for European biotech, pharma and drug development companies for several years.
- Multi-step synthesis of a single substance – PhD level competence and international experience in chemical synthesis of complicated bioactive compounds.
- Finding solutions for challenging synthetic problems and process development tasks.
- Rescue team for your project.



CORE EXPERTISE

- Anthracyclines
- Metabolites, intermediates, impurities for API
- Natural oligopeptides
- Fluorescent-labeled molecules
- Pheromones and unsaturated compounds
- Total synthesis of natural compounds
- Peptide linkers
- Amines, aminoacids and derivatives



Contract research: Micro- ja molekulaaribioloogia

Providing services for biotech industry:

- Development of the bacterial strains using molecular biology tools.
- Development of the bacterial strains by mutagenesis.
- Optimization of the conditions for the sporulation.
- Development of the bacterial fermentation.
- Process transfer to the customer's facilities.

Synergy of chemistry and biology:

- “one-stop-shop” services for interdisciplinary projects
- starting from genetic modifications up to fermentation and downstream



Contract research: DOWNSTREAM

- **Downstream = isolation of chemical compounds after fermentation**
- Downstream Unit: 4 persons (from them 2 PhD)
- Crystallization, extraction, chromatography
- High purity and quality requirements
- Development of purification technologies up to kilo scale



HIGHLIGHTS

- **Project Management System**

- Detailed calculation of the human resources usage
- Detailed calculation of the project time-schedule (with hour accuracy)

- Permanent internal controlling of using the resources
- Permanent internal reporting to the R&D/Business Development

- Quality control throughout the whole process

- **Communication with the customer**

- Weekly reporting and regular phone conferences
- A Project Manager and a Key Account Manager are assigned to every Project
- Our Key Account Managers and Project Managers are easily contacted by e-mail, phone or Skype



PRODUCTS

Rimantadine (antiviral)

Amrubicin (small cell lung cancer)

Zoledronic acid (osteoporosis)

E-Urocanic acid (skin treatment, anticancer)

Nordoxepin (metabolite of antidepressant Doxepin used in PET studies)

Pheromones :

- grapevine moth *Lobesia Botrana*
- apple moth *Cydia Pomonella*

TBD-Biodiscovery: Key Personnel

Dr. Andrus Tasa, PhD (Microbiology), CEO

Dr. Olga Tšubrik, PhD (Organic Chemistry), Head of Business Development

Prof. Ago Rinken, PhD (Bioorganic chemistry), Head of Quality Management, QP

Dr. Uno Mäeorg, PhD (Organic Chemistry), Senior Consulting

Mr. Oleg Lebedev, MSc (Organic Chemistry), Deputy Head BD/Project Manager

Dr. Ain Uustare, PhD (Bioorganic Chemistry), Head of Chemistry Department

Dr. Allan Nurk, PhD (Microbiology), Head of Microbiology Department

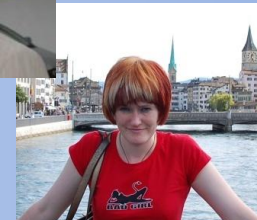
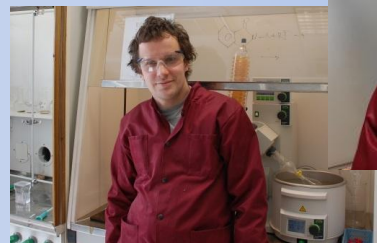
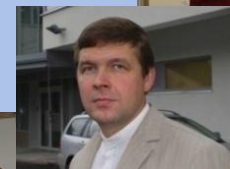
Dr. Imre Vallikivi, PhD (Organic Chemistry), Engineering/Project Manager

Dr. Marju Laars, PhD (Organic Chemistry), Head of Downstream

Mrs. Marju Kägo, MSc (Analytical Chemistry), Quality Assurance

Mr. Ivan Ogibalov, BSc (Organic Chemistry)

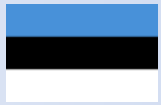
Mrs. Vilve Alt, MSc (Organic Chemistry)



PARTNERS AND CUSTOMERS WORLDWIDE



Austria



Estonia



Finland



France



Germany



Ireland



Israel



Italy



Latvia



Poland



Spain



Sweden



United Kingdom



USA



TBD-Biodiscovery: References

- Galilaeus OY (Finland). Dr. Kristiina Ylihonko (CEO)
- CABB (CABB Finland, former KemFine), Dr. Reijo Partanen
- R&D Biopharmaceuticals (Germany), Dr. Wolfgang Richter
- Aromalab (Germany), Dr. Michael Cappi
- Synthelor SAS (France), Dr. Jean-Christophe Henry (CEO)
- Joseph Fourier University (France), Dr. Valdur Saks
- Green Universe Agriculture (Spain), Mr. Ignacio Horche Trueba
- Galchimia (Spain), Dr. Jacobo Cruces
- Camida (UK), John McNeille
- Grindeks (Latvia), Mr. Eriks Ivanovskis
- Asper Biotech Ltd (Estonia), Dr. Ants Kurg (R&D)
- Renek Keemia OÜ (Estonia), Dr. Eke Roo (CEO)



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