



## SEARCH REPORT

### Identification of CMO Production Facilities

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All works described in this report have been done according to the state-of-the-art of information research.

*Document approved, May 29 2006*

A handwritten signature in black ink, which appears to read "Christian Velten". The signature is written in a cursive, flowing style.

(Dr. rer. nat. Christian Velten, project leader)



## 1. Question

Objective: Identification of Europe-based CMO facilities able to offer production capacities for class II microorganisms (GMP authorisation), size 1-1.5 m<sup>3</sup>, with optional postprocessing (centrifugation, separation, freezing, freeze-storage).

Search strategy:

Identification of putative CMOs that fit to the profile.

Contacting identified CMOs to verify relevancy.

Analysis and summarisation of data.

### 3. Research

In a first step we identified a set of companies that offer CMO production facilities. This initial list was checked for relevance by consulting publicly available company and facility information.

In a second step we contacted by email all CMOs of interest. Contacts that did not answer to the first try were contacted again by email and telephone. During all contacts we did not mention the name of the client. If you are going to talk to companies from the list yourself, you are free to reference our previous contacting (Mrs Anette Grieb from SCITARI).

Contacted companies include ... Analytical Biological Services Inc., Angel Biotechnology Ltd., Avecia, B. Braun Melsungen AG, Bavarian Nordic A/S, Baxter Pharmaceutical Solutions LLC, Bayer HealthCare AG, Ben Venue Laboratories, Bifodan A/S, Biomeva (formerly BioReliance), Biophélie, Boehringer Ingelheim, Cambrex Biopharmaceutical Services, Cardinal Health Contract Manufacturing, Cellgenix, Celliance Cooperation (formerly Sierra BioSource), Celonic GmbH, CTM Biotech, Cypex Limited, Diagnostics Scotland, Diosynth Inc., DowPharma, DSM Biologics, ERFA SA, EUFETS AG (a company of the Fresenius Biotech Group), EUGENEX Biotechnologies, EVOTEC OAI AG, EXBIO Praha a.s, Genzyme Pharmaceuticals, Girindus AG (belongs to Solvay), GlaxoSmithKline, HENOGEN S.A., Hospira One 2 One, Hovione, I.C.I. International Chemical Industry SpA, InVivo Biotech GmbH, Lonza Biologics Plc., Nextpharma, Novartis Behring (formerly Chiron Vaccines), Patheon, Pierrel, POLYMUN Scientific Immunbiologische Forschung, PolyPeptide Laboratories, Protein'eXpert, Rentschler, Rhodia ChiRex, SANDOZ GES.M.B.H. (belongs to Novartis), Sanofi Aventis, SellWiss and Strathmann Biotec AG.

We rated as positives ...

- companies that verified their data and their relevance (as defined by the objective of this research).

These are: Avecia, Bayer HealthCare AG, Biomeva, Diosynth Inc., DSM Biologics, I.C.I. International Chemical Industry SpA, Lonza Biologics Plc., SANDOZ GES.M.B.H. and Strathmann Biotec AG. Details and contacts see separate table document.

We rated as negatives ...

- companies that did not give any feedback,
- companies where the detailed facility parameters did not fit to the profile.

Details see separate table document.

Company	Contact	Country	Description	Production Facility Parameters
Avecia	<p>biotech@avecia.com  www.avecia.com/biotech  Koen Hellendoorn PhD  Commercial Development Manager, Avecia  Biotechnology,  PO Box 2, Belasis Avenue,  Billingham TS23 1YN, UK  Tel: + 44 (0) 1642 364165  Mobile + 44 (0) 7921 940178  Fax + 44 (0) 1642 364463  further contact: Tel: +44 (0)1642 363511,  Fax: +44 (0)1642 364463, Tel: + 44 (0)161  740 1460, Fax: + 44 (0)161 795 6005</p>	UK, US	<p>We have four independent cGMP manufacturing streams for the production of microbially expressed human therapeutics, which are purpose-designed for the manufacturing of multiple products. These facilities can also be used for the growth and separation of microbes, without subsequent protein purification. cGMP production line 1000 L stream (800 L working volume = ABC1000) is our most appropriate line for this inquiry. Mainly used for phase I / II manufacturing. We will be able to freeze the material.</p>	<p>The ABC1000 facility is the most appropriate for the project you described. This facility could be used for some class II micro organisms, but we would need further details before I could confirm whether we would be able to handle your client's strains.</p>
Bayer HealthCare AG	<p>Dr. Hans-Dietrich Hörlein,  Bayer HealthCare AG,  Product Supply Pharma,  Leader Biotechnology, 42096 Wuppertal  Tel: +49 (0)202 36 2357  Fax : +49 (0)202 36 7524  hans-dietrich.hoerlein@bayerhealthcare.com  http://www.bayerhealthcare.com  http://www.pharma-und-chemiepark.de  Dr. J. Michael Soeder, Leader of Bayer Industry Services GmbH &amp; Co. OHG, 51368  Leverkusen, Tel: +49 214 30 31930, Fax:  +49 214 30 31918  joerg-michael.soeder.js@bayerindustry.de</p>	Germany	<p>Contract manufacturer for microbiological products according to cGMP requirements.</p>	<p>The contract manufacturing requested is likely to be carried out. Prior to a final statement more details are needed.</p>

Biomeva formerly BioReliance	BioReliance Manufacturing GmbH Czernyring 22 D-69115 Heidelberg Tel: +49 (0)6221 90 26 0 Fax: +49 (0)6221 90 26 90 Thomas.Pultar@biomeva.de info@bioreliance.com BioReliance Ltd., Stirling FK9 4NF, UK Tel: +44 (0)1786 451 318 Fax: +44 (0)1786 464 764 Glasgow, UK, Tel: +44 (0)141 946 9999, Fax: +44 (0)141 946 0000	US, UK, Germany	Contract manufacturer for microbiological products according to cGMP requirements.	Generally they can do the CM but need further information.
Diosynth Inc.	Diosynth bv, P.O. Box 20, 5340 BH OSS, Phone:+31 412 661333, +31 412 662521, api@diosynth.com , Mr Eric van den Berg, eric.vandenberg@diosynth.com +31 412 661217 ; Peter van Straelen, Director Sales and Marketing, peter.vanstraelen@diosynth.com info@Diosynth-RTP.com	The Netherlands; USA, France	We offer production of recombinant proteins/peptides and DNA products for therapeutic and vaccine applications from mammalian and microbial expression systems etc.	We can run our reactors in Europe as low as 1600 L volume.
DSM Biologics	Dr. Christian Martin, DSM Pharma Chemicals, Account Manager, Emerging Pharma Europe Office: +31 (0) 46 47 73248 Fax: +31 (0) 46 47 73179, Mobile: +49 (0) 172 2440 199 Christian-G.Martin@dsm.com 6411 TE Heerlen (NL); Tel. +31 (45) 578 8111; Fax. +31 (45) 571 9753 ; www.dsmbiologics.com; info.biologics@dsm.com P.O. Box 43, 6130 AA Sittard, Tel. +31 (46) 4773275, Fax. +31 (46) 4773605, http://www.dsm.com CEO: Mr André Bos	The Netherlands, Canada, Italy	DSM Biologics, a business unit of DSM Pharmaceutical Products, is a global provider of manufacturing technology & services to the biopharmaceutical industry. In addition to offering world-class biopharmaceutical manufacturing services.	CM can be carried out.

I.C.I. International Chemical Industry SpA	Dr. Bruno Rotondi, Managing Director, I.C.I. International Chemical Industry SpA Via Cimarosa, 4, 20144 Milano, Italy, Tel: +39-02-4380051 Fax: +39-02-4819003 Secretary: rosy@finchimica.net Additional contact person: italo.costanzi@icispa.com	Italy	A fermentation pilot plant is presently under construction and this project should be finalised by October 2006. This project foresees the installation of four 2 lt fermentors, two 30 lt. fermentors, one 80 lt. fermentors and two 500 lt. fermentors. There is also the possibility to add further fermentors to reach a maximum capacity of 5000 lt. For the time being we are not planning on working with Class II micro-organisms but this could be possible. We do foresee that our future production will be according to GMP for human application. We are also planning to install a centrifuge, separation, freezing and freeze storage.	We are aware that in its present condition our structure is not perfectly in line with your customer's requests, however as the realisation is still underway, there is the possibility in the event of a cooperation agreement, to carry out any required up-grading.
Lonza Biologics Plc.	Dr. Michael Petersen Director Sales & Business Development / Lonza Custom Manufacturing Lonza Ltd, Muenchensteinerstr. 38, 4002 Basel, Switzerland, Tel. +41-61-316 8528 - Fax +41-61-316 9528 michael.petersen@lonza.com Tel +41 61 316 8359 contact@lonza.com 228 Bath Road, SL1 4DX Slough, Berkshire, Great Britain, Telephone +44 1753 777000, Fax +44 1753 777001 contact@lonza.co.uk www.lonzabiologics.com http://www.lonzabiotec.com	UK, US, Swit- zerland, Czech Republic	The world's leading contract manufacturer of monoclonal antibodies and recombinant proteins derived from mammalian cells. Lonza Biologics specializes in development and manufacturing services to meet the needs of the biotechnology and pharmaceutical industry.	We can offer CM in the Czech Republic according to your inquiry.
SANDOZ GES.M.B.H. Belongs to Novartis	Biochemiestr. 10, 6250 Kundl Tel: +43-5338/200-680 Fax: +43-5338/200-442 <a href="http://www.sandoz.at">http://www.sandoz.at</a> Herbert Knotz, Ph. D. Senior Manager Projects & Cooperations herbert.knotz@gx.novartis.com Dr. Gerhard Santer Head Cooperations DMAI Biochemiestrassen 10 A-6250 Kundl/Austria Phone:++43 5338 200 2972 Fax: ++ 43 5338 200 499 mobile: ++ 43 664 6104114 gerhard.santer@sandoz.com	Austria	Sandoz offers contract manufacturing. Sandoz manufactures for numerous cooperation partners pharmaceuticals and active ingredients for the biotechnology industry. More than 50 international companies trust in our experience.	CM can be carried out.

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Strathmann Biotec AG is a dynamic and expanding biotechnology company based in Hamburg, Germany. Founded in 1987 as Pharma Biotechnologie Hannover. Since 1997 it is part of the Strathmann Group and a subsidiary of Strathmann AG, a leading mid-sized pharmaceutical company in Germany. Today, Strathmann Biotec employs about 90 differently skilled experts for the development and manufacturing of biopharmaceuticals working together in interdisciplinary teams. We are a contract manufacturing organization specialized on microbial production.

We meet the required criteria.