# Dagmar Meissner

***SUMMARY***

Consultant with over 15 years of experience in the biotech field, including cell based therapies, biopolymers, sustained drug delivery, mammalian cell recovery, recombinant protein isolation with focus on Process Optimization and Scale-up, Technology Transfer, and Project Management.

***EXPERIENCE***

**BioProcess Solutions LLC, Owner** **2009- present**

Founded BioProcess Solutions in March 2009 and registered as LLC in July 2009. Providing consulting services in the areas of Process Development, Scale-up, Technology Transfer, and Project Management from preclinical through Phase III clinical studies. The following is a select list of recent consulting activities:

- Process characterization
- Person in plant for client process
- Process Validation (process validation master plan, PQ protocols, PQ validation report)
- Quality Risk Assessment (FMEA)
- IQ/OQ/PQ supporting activities
- Downstream process optimization for protein to reduce operating cost
- Downstream process optimization to remove animal derived feed stocks
- Protocol development for optimization experiments

**MicroIslet, Inc., San Diego, California (part-time basis)** **2006-2007**

***Director Preclinical Development***

Coordinated preclinical and regulatory efforts for a cell based therapy for Type 1 Diabetes:

- Project management of preclinical studies in preparation for IND. Responsible for rodent and primate studies at contract facilities, including writing/reviewing protocols and procedures, scheduling, and auditing.
- Responsible for the preparation and submission of a pre-IND package to the FDA. Active participant during pre-IND meeting with FDA.
- Responsible for writing, maintaining, and reviewing company operation timelines (MS project).
- Lead efforts for Process Development project to evaluate alternative alginate and chelator sources for the encapsulation of porcine islets.

**MicroIslet, Inc., San Diego, California** **2001 to 2005**

***Director, Process R&D***

Responsible for the process research and development efforts to prepare MicroIslet's encapsulation technology for IND enabling studies:

- Assembled and managed a process development team for process refinement.
- Developed and optimized the prototype encapsulation technology and demonstrated proof-of-concept in vivo. The process was based on the encapsulation of live tissue in alginate droplets using an electrostatic droplet generator. Material was prepared under aseptic conditions for implantation.
- Prepared and reviewed procedures, SOPs and batch records.
- Hired and managed scientist for analytical methods development. Assays included capsule diffusivity, capsule size, capsule strength, etc.
- Responsible for the preparation of product for safety and efficacy studies in animals.
- Co-Investigator in NIH SBIR grant.

**Monsanto/CP Kelco (formerly Kelco Biopolymers), San Diego, California** **1998 to 2000**

***Senior Scientist, Process R&D***

Management and process leader position covering a variety of products:

- Designed and optimized a manufacturing process for the isolation of active natural components from food sources for use in nutritional supplements. Scaled up process and conducted initial feasibility manufacturing runs at a contract facility.
- Project leader for novel food biopolymer products coordinating efforts across multiple disciplines. Lead process development efforts to develop a recovery process eliminating off-flavor formation for a food biopolymer product (gellan gum). Completed scale-up of this process to commercial scale. Efforts resulted in pending patent.
- Assisted in the scale-up and transfer to GMP for the production of sterile ultrapurified alginate product for pharmaceutical applications. Prepared GMP documentation for the process (SOPs and batch records).

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**Pacira Pharmaceuticals (formerly DepoTech Corp), San Diego, California** **1994 to 1998**

***Senior Process Engineer/Process Engineer, Process Development***

Process optimization and scale-up for DepoFoam sustained drug delivery products. The technology is based on liposomes formed by a double emulsion process using high shear mixers followed by a purification and formulation step using microfiltration.

- Collaborated in the scale-up and optimization of the DepoCyt process (for the intrathecal treatment of lymphomatous meningitis).
- Instrumental in the design, installation, commissioning and validation of the aseptic automated process equipment for DepoCyt consisting of high shear emulsion system, tangential flow filtration, CIP/SIP, etc...
- Developed GMP SOPs and batch records, and provided training.
- Lead a team for the preparation of the first clinical batches of DepoCyt.
- Provided technical support for GMP Manufacturing.
- Designed small scale automated process equipment for Process R&D purposes.
- Investigated alternative technologies for the preparation of emulsion-based DepoFoam products. Efforts resulted in various presentations and one pending patent.
- Managed a group of interns and Process Development associates in optimization studies.

**Biogen Inc., Cambridge Massachusetts** **1992 to 1994**

***Senior Process Associate/Process Associate, Process Development***

Process development for cGMP production of biologics (Beta Interferon, Hirulog, LFA3-TIP, etc.):

- Unit operations included mammalian cell culture, bacterial fermentation, clarification, protein purification
- Designed and performed laboratory and pilot scale experimentation for process development and scale-up.
- Specified, designed, and implemented clarification system for mammalian cell cultures for phase 1 clinical production.
- Assisted in the procurement, installation, and validation of process equipment for the ß-Interferon clinical production.
- Involved in technology transfer to GMP facility (documentation and validation of cell recovery processes for Phase I trials)

# Dagmar Meissner

## *EDUCATION*

***M.S. Chemical Engineering;*** *Tufts University, Medford, Massachusetts, 1992*
Thesis: "Analyze and model the secretion mechanism of glucoamylase in filamentous fungi"

***Diploma in Chemical Engineering;*** *Fachhochschule für Technik Mannheim (PolyTechnic), Germany, 1989.*
Thesis: "Synthesis and characterization of low extractable reverse phase materials for HPLC – Carbamate bonded diol silica."

## *LANGUAGE SKILLS*

Bilingual in English and German. Fluent in French.

References Available Upon Request

## *PUBLICATIONS*

### *Presentations and Abstracts*

1. Gaudet, I., Dunkelman, N., Szabo, A., LaFontaine, E., **Meissner, D**., Bartel, R. (2006). Islet Transplantation Dosing Based on Viable Beta Cell Analysis. Levine Symposium 2006.
2. Bartel, R, **Meissner, D.,** Dunkelman, N., Krotz, J., Brignolo, L., Salomon, D. (2006). Characterization of Encapsulated Porcine Islets and Long Term Function in Diabetic Non-Human Primates without Prolonged Immunosuppression. Levine Symposium 2006.
3. Bartel, R, Ospina, H., **Meissner, D.,** Stuiver, I., Witte, R., Krotz, J., Salomon, D. (2005). Encapsulated Porcine Islets Treated with a Cocktail of Survival Factors Function Long-Term in Diabetic Lewis Rats. Levine Symposium 2005
4. Bartel, R, Ospina, H., **Meissner, D.,** Stuiver, I., Witte, R., Krotz, J., Salomon, D. (2005). Encapsulated Porcine Islets Treated with a Cocktail of Survival Factors Function Long-Term in Diabetic Lewis Rats. XenoTransplantation Congress, 2005
5. **Meissner, D.**, Stuiver, I., Szabo, A., Evanoff, G. Miller, E., Salomon, D. (2004). Microencapsulated Adult Porcine Islets Using MicroIslet's Proprietary Formulation MPF2. NIH Encapsulation workshop Mar 28-29.
6. Stuiver, I. **Meissner, D**., Szabo, A., Evanoff, G. Miller, E., Salomon, D. (2004). Naked and Encapsulated Adult Porcine Islets Render NOD/SCID Mice Normoglycemic. NIH Encapsulation workshop Mar 28-29. Invited speaker.
7. Szabo, A., Stuiver, I. **Meissner, D**., Evanoff, G. Miller, E., Salomon, D. (2004). Successful Function of Microencapsulated Porcine Islets in Streptozotocin Diabetic Immuncompetent Mice. ATC Conference, Boston May 14-18, 2004.
8. Stuiver, I, Szabo, A., **Meissner, D**., Evanoff, G. Miller, E., Salomon, D. (2003). Microencapsulated Adult Porcine Islets Render Streptozotocin-Diabetic Immunoincompetent and Immunocompetent Mouse Strains Normoglycemic. Seventh International Xenotransplantation Congress, 2003.

9. Stuiver, I, Szabo, A., **Meissner, D**., Evanoff, G. Miller, E., Salomon, D. (2003). Microencapsulated Adult Porcine Islets Render Streptozotocin-Diabetic Immunoincompetent Mouse Strains Normoglycemic. Levine Symposium. Nov. 4-7, 2003.
10. Pepper, C., Patel, M., **Meissner, D**., Tran, T., Hartounian, H.: "DepoFoam™, Drug Delivery Manufacture: Issues in Process Development." *Biochemical Engineering 10th Annual Meeting*, Kananaskis, Alberta, Canada 1997
11. **Meissner, D**., Reyes, C., Brewer, A., Patel, M., Hartounian: "Application for Unsteady Flow Patterns in Permeate and Retentate for the Diafiltration of Multivesicular Liposomes." *American Institute of Chemical Engineers*, Anaheim, CA, 1997
12. **Meissner, D**., Hartounian, H.: "Independent Viscosity as a Tool for Scaling-Up Water-Oil Emulsions." *American Institute of Chemical Engineers*, Anaheim, CA, 1997
13. Pepper, C., Patel, M., **Meissner, D.,** Brewer, A., Hartounian, H.: "Process Development Considerations of Multiple Pass Sterile Cross Flow Filtration Operations." *Biochemical Engineering 10th Annual Meeting*, Kananaskis, Alberta, Canada 1997
14. **Meissner, D**., Reyes, C., Hartounian: "Application for High Frequency Backpulsing in Diafiltration of Multivesicular Liposomes." *North American Membrane Society*, Baltimore, MD, 1997
15. **Meissner, D**., Patel, M., Hartounian, H.: "Design, Installation, and Validation of an Automated Aseptic Biopharmaceutical Process for a Multi-Use Pilot Plant Facility." *American Institute of Chemical Engineers*, Chicago, IL, 1996
16. **Meissner, D**., Patel, M., Shanklin, T., Hartounian, H.: "Scale-Up Considerations for Developing an Aseptic Diafiltration Process for Water-Oil-Water Emulsions." *American Institute of Chemical Engineers*, Chicago, IL, 1996
17. Patel, M., **Meissner, D**., Hartounian, H.: "Development of an Integrated Biopharmaceutical Process Automation System." *American Chemical Society*, New Orleans, LA, 1996
18. Levy, P.F., **Meissner, D**.: Development and Scale-up of a Crossflow Microfiltration Process for Clarification of Mammalian Cell Conditioned Media." *ASME Conference* 1993

*Patents*

1. Bower, S., Burke, E., Harding, N., Patel, I., Schneider, C., **Meissner, D**., Morrison, N., Bezanson, R.:"Clarification of sphingans and compositions thereof, CP Kelco, US Patent 7,887,866
2. Bower, S., Burke, E., Harding, N., Patel, I., Schneider, C., **Meissner, D**., Morrison, N., Bezanson, R.:"Mutant bacterial strain of the genus Sphingomonas deficient in production of poly-hydroxy butyrate and a process of clarification and composition". CP Kelco, US patent 7,829,697, World patent pending WO/2001/064897, European patent granted EP1261717
3. Hartounian, H. **Meissner, D**., Pepper, C, "Production of Multivesicular Liposomes." , DepoTech, US Patent Pending US20020039596, US20070235889, World Patent pending (WO 99/25319), European patent pending EP1030652

***Grants***

1. 2005-2008 NIH SBIR Phase II entitled: Encapsulated Porcine Islets into Rhesus Macaques for the study of the safety and efficacy of encapsulated porcine islet transplantation in non-human primates. Funding for 3 years. $1,700,000. PI: Stuiver, I., Co-Investigator: **Meissner, D.**
2. 2003-2004 NIH SBIR Phase I entitled "Optimization & Automation of Pancreatic Islet Isolation" to study porcine islet isolation processes. Funding for 6 months $150,000. PI: Stuiver, I., Co- Investigator: **Meissner, D.**