This Lyophilization Partners list is provided as a reference of industry experts for our customers seeking assistance with any aspect of their freeze-drying projects.

Please note consultants listed are not commercially affiliated with SP and offer independent consultancy and other services. If you are a consultant with a lyophilization focus and would like to be included, please contact us at: hello@spindustries.com.

#### **Biopharma Group**

#### biopharma.co.uk



The R&D consultancy and analytical lab services division of Biopharma Group is headed up by Director of R&D. Dr Kevin Ward, who previously worked at Pfizer Central Research and as a Research Fellow in vaccine development at Aston University having received his PhD for investigations into the freeze drying of pharmaceutical formulations and drug/vaccine delivery systems. Dr Ward lectures extensively on freeze drying processes, best practices, and technologies both as part of Biopharma's freeze-drying training courses - scheduled and customized - and as a regular on the conference circuit, as well as having been an industrial supervisor to PhD students. Established in 1997, Biopharma's R&D division provides independent R&D, lyo-analysis, process development services, training courses and analytical instrumentation to the global customer base. Together with our knowledge of freeze drying, we offer a uniquely comprehensive service, including consultancy packages, covering all aspects of freeze-drying from pre-formulation studies through to production and dried product analysis. Biopharma Group is a leading supplier of equipment for freeze-drying and associated processing technologies, R&D consultancy, and analytical lab services to the pharmaceutical, biotech and process industries. Our aim is to provide equipment and services that best meet your process requirements and to remain onhand for assistance thereafter.

#### Comecer

#### comecer.com



Comecer custom API processing and containment equipment in isolators is designed to handle, transfer, produce, dispense pharma APIs, HAPIs, and PAPI. Comecer designs and builds API Processing equipment for pharma drug manufacturing operations. Comecer's full range of custom machines and systems meet many of the requirements in a pharma manufacturing plant or laboratory, with guaranteed asepsis, operator safety and GMP compliance. The solutions are based on isolators and address many processes.

## Dr. Indu Javeri, PhD - CuriRx





CuriRx Inc is a Contract Research and Product Development Service Company specializing in the area of Formulation and Analytical development. We have tremendous experience in developing lyophilization cycle that can be transferred to CMO. We also have the capacity to manufacture non-GMP vials for supporting animal studies and non-GMP stability studies. Scientist at CuriRx have successfully developed formulations for pharmaceuticals (small molecule), peptides, biopharmaceuticals(large molecules), antibodies, generics, vaccines, and biosimilar products. We also offer consultancy in the areas of product development, process development, troubleshooting process or analytical methods, business strategies and GMP compliances.

#### Dr. Henning Gieseler, PhD & Dr. Margit Gieseler, PhD - GILYOS GmbH

#### freeze-drying.eu | gilyos.com



Dr. Henning Gieseler is a licensed pharmacist in Germany since 2000 and received his PhD in 2004 at the Department of Pharmaceutics, University of Erlangen (Prof. G. W. Lee) with the thesis: Product Morphology and Drying Behaviour delineated by a new Freeze-Drying Microbalance. After a post-doctoral research period at the School of Pharmacy, University of Connecticut (Prof. Michael J. Pikal) until early 2006, he returned to Erlangen where he established the Freeze-Drying Focus Group within the Division of Pharmaceutics. His current research interests include process analytical technologies (PAT) for freeze-drying, methodologies to determine a representative critical temperature of a given formulation with focus on freeze dry microscopy (FDM) and differential scanning calorimetry (DSC), heat and mass transfer when drying from atypical product container systems and small product volumes, formulation of proteins and peptides, and (5) freeze drying of nanomaterials.

GILYOS (composed of the words Gleseler LYOphilization Solutions) was formed in late 2010 to provide consulting and contract development services in the field of freeze-drying (lyophilization) to the global pharmaceutical and food industry. The service portfolio of GILYOS comprises true in-depth expertise in freeze-drying science and application of this technology to various pharmaceutical products, food products and other materials. The key area of expertise of GILYOS is freeze-drying process development and optimization which is supported by cutting-edge process analytical technology (PAT) tools for freeze-drying. With experience and technical knowledge of different scales in freeze-drying equipment, GILYOS can offer a comprehensive development service from early formulation development through scale-up to manufacturing. Importantly, GILYOS applies analytical procedures throughout the development process to fully assess product performance characteristics in the frozen and dried state.



### Dr. Jeff Schwegman, PhD - Labyrinth Biopharma, LLC



lab-bp.com

J. Jeff Schwegman, Ph.D. is currently the founder and chief executive officer of Labyrinth Biopharma, where he specializes in speaking and consulting in parenteral pre-formulation, formulation, analytical, and lyophilization of both small molecules and large biomolecules. He is also currently the Course Director for the Center for Professional Advancement where he teaches the Lyophilization Technology course in the United States and at various locations in Europe. In addition, he holds several patents and develops new technologies in lyophilization science.

#### Lyophilization Technology, Inc.

#### lyotechnology.com



Since its inception in 1992, the company has grown to provide a wide variety of services in diverse applications, drawing on a breadth of experience, depth of science, and extensive expertise. The mandates for the organization are to provide a source of services, from early development through Phase II clinical trial materials, assisting in bringing a new product to the health care industry. Technical support and services also provide facilitation for commercial manufacturing operations through consulting and training. The practical application of experience is coupled with interests in applied research and advancing the technology. This combination of research and commercial enterprise offers the industry a unique source of comprehensive expertise that spans bringing a new product to market increasing the productivity of existing operations.

#### Dr. Karen Bossert, PhD, RpH

#### kabossert@verizon.net

Experienced and versatile professional specializing in Manufacturing Development of Sterile Products, with added focus in Lyophilization and support for Quality and Manufacturing Operations, from pre¬ clinical development through commercialization. Specializations include Manufacturing Development; Person-in-Plant; Product and Process Design; Technology Transfer & Scale-up; Manufacturing Operations; Quality Assurance; Quality Agreements; Training; Audits; Documentation; and Validation.

# The list below is provided as an additional source of companies that offer products commonly utilized in freeze-drying, but not offered by SP.



# Flow Sciences, Inc. flowsciences.com

Design and manufacture of containment solutions



## WL Gore & Associates gore.com

GORE® LYOGUARD® freeze-drying trays



## Tempris GmbH tempris.com

Real-time product temperature monitoring in freezedrying



#### GBA gbateam.com

Facility design and process engineering



#### Metrohm ic.metrohmusa.com

Titration and ion chromatography workflow



# West Pharmaceutical Services, Inc. westpharma.com

Drug delivery devices & laboratory services

