



Chemistry Playbook™

Proven, Modular, Expedited CMC Solutions from Carbon to Commercialization

Have you ever stopped to ask the question “Why aren’t my outsourced service providers talking to each other?” It sounds like common sense that service providers are communicating, discussing timelines and setting expectations for project flow. The simple fact is that service providers typically don’t talk to each other, and this is one of the leading causes of project delay.

Chemistry Playbook™ specifically addresses this issue. We came together as a consortium of expert client-focused companies to open lines of communication and provide a better drug development experience for our clients.

Our guarantee: THE HANDOFFS BETWEEN CHEMISTRY PLAYBOOK MEMBERS WILL BE MARKEDLY BETTER THAN WHAT YOU’VE EXPERIENCED WITH INDIVIDUAL SERVICE PROVIDERS IN THE PAST.

- We’ve designed the plays to fit the situation – We understand that each project is unique, and needs to be treated as such. From Gantt charts and timelines to handoffs, for individuals or the entire team; we’ve got the process worked out.
- We’re world class CMC athletes working under the right leadership. From CEO-level program support to integrated program management to standardized commercial documents, we’ve handled the detail so that you don’t have to.
- Plug-and-Play or partner with “The Playbook” – This flexible model streamlines product development through integrated communication.
 - Access Beckloff Associates for regulatory oversight,
 - Cambridge Major Laboratories for API,
 - Avantium Pharma for solid form selection / crystallization process optimization, and
 - Xcelience for formulation development and drug product manufacturing expertise.

Recently, we have added two new partners to the Chemistry Playbook™ alliance:

- Micron Technologies for particle size reduction and analytical laboratory services, and
- MPI Research for comprehensive discovery, safety evaluation, bioanalytical / analytical services.

For more information about Chemistry Playbook™, please contact info@theplaybook.com or select a specific point of contact from the list of alliance partners on the back of this brochure.

Cambridge Major Laboratories, Inc. – US

W130N10497 Washington Drive | Germantown, WI 53022 | www.c-mlabs.com

Primary Contact: Brian W. Scanlan, Chief Business Officer | b.scanlan@c-mlabs.com | (262) 251-5044 x 304

Cambridge Major Laboratories provides advanced chemistry services to the world's leading pharmaceutical and biotechnology companies. We boast an impeccable reputation for delivering some of the most challenging projects and meeting the tightest timelines. And Cambridge Major's reach is truly global in nature, operating four facilities in the US and Europe, serving hundreds of companies across the world.

Xcelience, LLC

5415 W. Laurel Street | Tampa, FL 33607 | www.xcelience.com

Primary Contact: Derek G. Hennecke, CEO & President | Derek.hennecke@xcelience.com | (813) 286-0404 x 112

Xcelience is a premier provider of formulation development and manufacturing solutions, delivering API characterization, analytical, dosage form development and clinical trial manufacturing, packaging and labeling services since 1997. A market leader for powder-into-capsule (PIC) services, Xcelience has processed more than 40 APIs and 130 clinical supply batches. With four systems operating globally, we offer greater capacity than any other provider. Xcelience is renowned for reliably expediting early development activities to speed potential drugs to clinical trials, while applying stage-specific scientific knowledge and experience.

Beckloff Associates

7400 W. 110th Street Commerce Plaza II Suite 300 | Overland Park, KS 66210 | www.cardinalhealth.com/beckloff/

Primary Contact: Michael Beckloff, President | mbeckloff@beckloff.com | (913) 451-3955

Beckloff Associates is a full-service pharmaceutical research and development regulatory consulting firm that specializes in helping pharmaceutical, biotechnology and medical device companies obtain timely and comprehensive regulatory approval. With our over eighty employees, our expertise and influence extends from the US market to the Canadian and European markets.

Micron Technologies

435 Creamery Way | Exton, PA 19341 | www.microntech.com

Crossways Blvd. | Crossways, Dartford, Kent, DA2 6QY | UK

Primary Contact: Joseph D. Drost, President|jdrost@microntech.com | (610) 425-5181

Micron Technologies, Inc. provides contract particle size reduction and analytical laboratory services exclusively for the pharmaceutical industry. With compatible FDA inspected facilities located in the United States and the United Kingdom, project scale up and processing can be undertaken in both facilities. Analytical capabilities include but are not limited to; particle size analysis, surface area, XRD, microscopy, method development and release testing.

MPI Research

54943 North Main Street | Mattawan, MI 49071 | www.mpiresearch.com

Primary Contact: Stephen W. Frantz, Ph.D, D.A.B.T | Stephen.frantz@mpiresearch.com | (269) 668-3336 x 1487

MPI Research exists to provide comprehensive discovery, safety evaluation, bioanalytical, and analytical services that meet the requirements of biopharmaceutical, medical device, animal health, and chemical companies as we partner globally to bring safer and more effective products to the world.