Karen Bossert, Ph.D., R.Ph. **List of Services**

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.

Manufacturing Development	Provide resource for design, oversight, and review of scientific projects to support implementation of new products and continuation of existing manufacturing operations.
Person-in-Plant	Provide presence of experienced professional in manufacturing facility during batch manufacture, testing and related activities.
Product and Process Design	Provide consulting services to perform independent review of formulation and process design. Assist in identification of suitable contract development services; provide oversight, as needed.
Technology Transfer / Scale-up	Design, review and oversight of technology transfer and scale-up activities due to changes in manufacturing site, equipment, or scale of operations. Prepare and review summary reports and "know-how" documents.
Manufacturing Operations	Assist with identification and qualification of appropriate contract manufacturing and testing sites for clinical and commercial materials. Provide oversight of contract operations, as desired.
Quality Assurance	Provide on-site or remote resource of experienced professional to assist with Quality operations at any level.
Quality Agreements	Prepare and review agreements to define appropriate quality aspects for contract relationships for product manufacture or testing and related GMP activities.
Training	Provide on-site training in areas of lyophilization, sterile product development and manufacture, and validation. Training can be as traditional lecture-based classroom training, or hands-on, as desired.
Audits	Perform audits of manufacturing and laboratory operations and service or material providers in support of contractor qualification or compliance assessment for existing operations.
Documentation	Provide resource for preparation and review of documents for cGMP activities, including Standard Operating Procedures, Master Batch records, executed batch records, calibration records, material specifications, stability protocols and summary reports, and change control documents.
Validation	Provide consulting service for design and review of validation strategy and activities, including preparation of Master Plans, studies to support appropriate Stage activities and qualification of manufacturing equipment and laboratory instruments. Provide hands-on resource as needed to execute or manage activities.