# BioPharmaDev

*Our Quality Services = Your Peace of Mind*

**BioPharmaDev, Inc.** is a CRO (Contract Research Organization) company servicing pharmaceutical, biotech, medical device, and dietary supplements companies with and without cGMP requirements.

**Our Strengths:** We are very experienced and knowledgeable in analytical method development/validation and product development for drugs and dietary supplements under cGMP environments, particularly working with FDA for submissions and inspections. We have built a high quality standard cGMP lab. We have strong backgrounds in technical, compliance, cGMP quality, managerial, and project management areas.

**About the funder:** Dr. Yan-Bo Yang has over 30 years of experience in analytical chemistry, particularly in separation sciences and chromatography technology for pharmaceutical, nutrition supplement, medical device, and biotech applications for both small molecules and large biologics. Dr. Yang is knowledgeable in drug product development, cGMP, quality systems, and preparation for FDA submissions. Prior to funding BioPharmaDev, Inc., Dr. Yang was Director of the Pharmaceutical Development at B. Braun Medical, Inc. Throughout his over 13 years of leadership and responsibility, no chemistry-related deficiencies, particularly those related to analytical methods, and no inspection observations (483s) for the Pharmaceutical Development Lab were given by the FDA from a large number of submissions and many inspections. Before joining B. Braun Medical, Inc., Dr. Yang was Director of Research at The Separations Group, Inc. developing various novel HPLC columns and studying separation theories and applications. The technical knowledge, quality standards, and track record of Dr. Yang help assure you that your job and project will be done to your satisfaction with peace of mind.

Dr. Yang serves as the president of AOAC International Southern California Section, member of the USP Prescription/Nonprescription (PNP) Stakeholder Forum Planning Committee, and chair of the USP 2012 PNP Stakeholder Forum. Dr. Yang helped found the Chinese-American Chromatography Association (CACA) and served as president for its first two terms. Dr. Yang is also the president of the Sino-American Biomedical and Pharmaceutical Professional Association (SABPA) OCLA chapter.

**We are providing the following services**.

1. Chemical sample analyses
   Analyze both small molecules and large biologics timely and accurately for pharmaceutical, biotech, medical device, and dietary supplement companies using such instruments as HPLC and GC .
2. Drug product development under cGMP requirements
   Perform in all areas of drug finished product development:
   - analytical method (both assay and impurities) development and validation,

- analytical method transfer,
- raw material qualifications,
- formulation and formulation feasibility stability study,
- API and drug product specification developments,
- stability study, and
- drug compatibility study with excipients and packaging/closure materials.

3. Drug development R&D studies
   Provide analytical services supporting drug product development at all stages and existing products under production.
4. Formulation development for Injectables products
5. Drug product packaging materials
   - Working with material vendors to select materials with desired specifications,
   - Guiding and helping obtain basic information from material vendors,
   - Study and analyze extractables and leachables.
6. Separation and/or Purification procedure/process development
   Separate and/or purify both small molecules and large biologics (e.g.: proteins, DNA, antibodies, polypeptides) timely and efficiently for pharmaceutical, biotech, medical device, and dietary supplement companies.
7. Extractable/leachables studies and analyses for pharmaceutical, biotech, medical device, and dietary supplement companies.
8. Short term feasibility stability studies.
9. Method development, method validation and testing of Dietary Supplement/Botanical products under cGMP environments.
10. Consultations
    - Consultations on optimizing and/or establishing a high quality cGMP system.
    - Consultations for the entire drug product development process/strategy and preparations for FDA submissions.

**Our Commitments:** Providing high quality services and peace of mind for our clients differentiates us from others. We are a team member of your project team.

**Contact:** If you have (and/or know anyone who has) any needs for these services, please feel free to contact:

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