

BrHM Prides Itself on
Thinking Outside the Box with the Goal of
Saving Time and Money While Ultimately
Receiving Timely Approval

Regulatory /Compliance Development Consulting with:

- 7 NDAs Submitted and Approved
- ~\$20 Billion Peak Annual Sales for Products Developed/Approved
- Multiple therapeutic area track-record, ie. cardiovascular, central nervous system, dermatology hepatology, oncology, metabolism/endocrine, nuclear imaging, thrombosis, etc.
- Experience with small molecules, biologics, peptides, proteins, oligonucleotides, medical devices and diagnostics, supplements and herbal products
- Supports Analytical Development and GMP Education for Natural Health Products
- Experience with priority review, fast track, accelerated approval, orphan drug, user fee waivers, etc.
- Successful manufacturing of “historical pharmaceutical development products” for current submissions of genetically targeted clinical indications
- COLOBIOSCIENCE Preferred Provider

Cassandra MacArthur, PM – CEO and
President of Project Management and Compliance

Cassandra’s experience includes development of small molecules, proteins, peptides, oligonucleotides, diagnostics and medical device products. Ms. MacArthur has successfully directed with hands-on expertise Non-Human Primate Pre-Clinical Irradiation studies in China using Colbalt-60.

Ms. MacArthur’s senior management positions include CMC, Project Management, Regulatory and Quality, in addition to a successful career in basic research at the Salk Institute for Basic Research and the Scripps Clinic and Research Foundation. Her Project Management skills have launched multiple international manufacturing and pre-clinical sites.

Prior Clients Include:

- ARCA Biopharma
- AVEVA Drug Delivery Systems
- Cell>Point, LLC
- Colorado Prevention Center
- Helicon Therapeutics, Inc.
- ISIS Pharmaceuticals
- Neurokey A/S, Denmark
- Sanofi-Aventis
- Upsher-Smith Laboratories
- ISO-Tex Diagnostics, Inc.
- Cleveland BioLabs, Inc.



**BRIDGING
HEALTH-MATTERS, LLC.**

**THE BRIDGE
FROM
RESEARCH
TO
DEVELOPMENT
AND
BEYOND**

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Comprehensive Compliance Development Services

Quality	Clinical	Regulatory	Pre-clinical	Special Services
<ul style="list-style-type: none"> • Quality systems development and integration as Quality by Design • CMO Facilities analysis and Quality GLP, and GMP audits including analytical and bio-analytical methodology • SOPs and all Quality documentation for GMP, GLP and GCP • Quality assessment and audits for all contract organizations • FDA audit training & preparation • Specification and Stability Program Development • Quality Assurance Consulting • Deviation and OOS (CAPA) programs 	<ul style="list-style-type: none"> • Clinical Operations • CRO selection & Project Management • IND, IDE and NDA clinical summary documents planning and analysis • Informed consent • Medical writing and editing <p>CMC-Manufacturing</p> <ul style="list-style-type: none"> • CTL and CMO selection including audit and “Gap analysis” • Project Management of manufacturing, analytical testing, etc. • CMC Dossier Development and Review • Quality Agreements and DMF Review 	<ul style="list-style-type: none"> • Strategic Regulatory Product Development Plans Providing Guidance from initial compound discovery through FDA Approval • Custom Target Profiles • Post-Approval supplements and amendments • Health authority strategy, meetings and negotiations (EMEA, FDA, TPD, Mexico, Australia, etc.) • Dossier (IND, ANDA, CTX, NDA, MAA, eCTD, BLA, 510(k), IDE, PMA, etc) strategy, and Project Management over site and preparation • Strategic dossier prosecution • Dispute resolutions, compliance issue responses • Strategic writing of background packages • Orphan drug and fast track applications • Authorized International US representation 	<ul style="list-style-type: none"> • Custom designed pre-clinical strategic development programs • GLP facilities section and Project Management • Targeted cGMP and cGLP implementation and compliance documentation • Data and pre-clinical report supervision 	<ul style="list-style-type: none"> • Regulatory due diligence for investors, partnerships, etc • System “gap analyses” and implementation • Training on Quality, Product Development and Regulatory requirements • Senior Management advising & Interim corporate staffing