CONSULTING SERVICES

Lisa Phillips Johnson is a Regulatory and Quality Systems Consultant for Innovative Blood Resources

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MT(ASCP)SBB, CQA, CQM/OE, RAC

Regulatory and Quality Systems Consultant

At Innovative Blood Resources we realize developing and integrating robust operational systems to meet regulatory requirements and effectively implement quality principles can strain resources. We are pleased to offer a solution: the consulting services of Lisa Phillips Johnson, a regulatory compliance and quality system expert.

Lisa has over 20 years of expertise implementing FDA (cGMP, cGTP, IND, BLA), CLIA and other standards-driven, industry requirements, most notably in the blood, HCT/P (cells/tissues) and research settings. She is recognized as a global leader for her contributions particularly in the cellular therapy arena.

PROFESSIONAL ACCOMPLISHMENTS

- Experienced speaker (presenting at AABB, ISCT, WMDA, NMDP) and contributor to industry and standard-setting organizations
- Developed, implemented and managed systems to support regulatory compliance and FDA submissions for biological products subject to FDA IND, BLA and IRB requirements
- Developed, implemented and managed effective quality systems, including SOPs/documents, training, CAPA systems and metrics, process improvement, recall management, change control and record management
- As Director of Regulatory Compliance at the National Marrow Donor Program, developed, implemented and managed cGMP/cGTP system and supplier audits to assess requirements for cellular therapy products under IND for over 200 U.S. and international manufacturing and testing sites

MEETING YOUR NEEDS FOR ORGANIZATIONAL SUCCESS

- Prepare and manage regulatory submissions for products subject to IND or BLA requirements (amendments/ supplements, annual reports, adverse events, BPDRs, recalls, cost recovery)
- Prepare for and host FDA and other inspections/audits; prepare audit responses (for citations such as 483s)
- Negotiate corrective actions at national and local levels for official inquiries and letters from FDA
- Create or enhance corrective and preventative action systems for process improvement
- Develop internal or supplier audit tools to support compliance with regulatory and industry standards or customer requirements
- Assess and implement effective processes for donor screening and testing
- Serve as out-sourced interim leadership for quality and regulatory functions or quality unit
- Develop and execute or review equipment and/or process validation protocols
- Develop or review policies and procedures to ensure compliance with regulations and industry requirements
- Provide training and education for staff and leadership to understand regulatory and quality concepts
- Mentor internal teams to build quality processes from the inside out

INNOVATIVE BLOOD RESOURCES

InnovativeBloodResources.org
1-888-980-8847

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For more information please contact:

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