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## Highlights

- Manage your risk with IBM's IT and GxP compliance expertise
  - Effectively qualify and validate components in a compliant manner
  - Increase efficiency with IBM's broad range of innovative products and services
  - Manage costs and increase infrastructure capabilities to support new business models
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# IBM Life Science Global Regulatory Center of Excellence

*Infusing IBM's Life Science managed services with the capabilities to enhance regulatory GxP compliance*

Today's Life Science companies are transforming their business to focus resources on more rapid research and development of new products, which requires dramatic innovation and optimization of the underlying information technology infrastructure. The ability to effectively implement this technology while adopting new business models, including new approaches to regulatory compliance, provides companies a competitive advantage through increased efficiency.

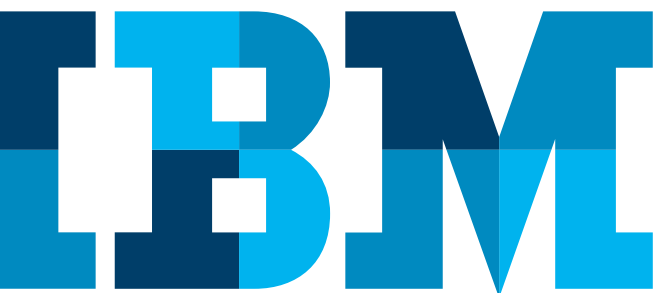
## **New business models require higher-value information technology approaches**

The adoption of cloud computing, data analytics, social media, and mobility enables collaboration and rapid decision-making to achieve business benefits faster with enhanced efficiency. Adoption of these new technologies requires a thorough understanding of regulatory requirements and a strategy to implement using both new and proven models such as cloud and traditional outsourced hosting.

## **Understanding challenges and designing innovative solutions helps maximize efficiency and enhance compliance**

IBM understands the challenges life science companies face and can address your needs by providing managed service infrastructure hosting or by adopting new, innovative technologies like cloud computing. IBM has extensive experience in hosting infrastructure in our facilities. IBM has also developed a comprehensive managed service deployment model for rapid adoption and compliant use of cloud computing.

By combining IBM's technical innovation and experience with the industry expertise of the Life Science Global Regulatory Center of Excellence, IBM can offer you solutions that provide transformational computing solutions with a GxP (i.e., Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice) compliant focus.



## Critical elements of life science services provide transformational solutions

- Deep industry **expertise** and understanding of regulatory requirements across the globe (e.g., FDA, EMA, MHLW)
- Highly **skilled**, trained personnel to perform services consistent with complex life science requirements
- Services provided through an industry leading **quality management system** functions as the core of IBM's life science compliance program as well as an extension of your compliance program
- Framework of best **processes and procedures** integrated with service **toolset** to address regulatory requirements
- World-class **toolset** to support workflows, ease of access, and documentation requirements consistent with GxP regulations, FDA's 21 CFR Part 11 requirements and EMA's Annex 11
- Compliant life science **cloud solution** that enables transformation of computing environments

## Why IBM?

IBM understands information technology in the life science industry and can help address your organization's needs and requirements to sustain compliance as both technology and regulations evolve. IBM can also implement the latest technological solutions with an experienced team of life science industry compliance professionals.

IBM's global reach and diverse products and services help enable life science companies to implement innovative technology in a globally consistent and compliant manner. Life science companies can improve efficiency, lower cost, and focus on their core business by integrating IBM's cloud computing, data analytics, mobility services, social media, security and IT risk management products and services into their enterprise.

IBM's Life Science Global Regulatory Center of Excellence enables you to focus on innovating new products while IBM's experienced industry professionals are effectively managing your technology. These capabilities can help your enterprise better manage regulatory compliance and risks and drive competitive business advantage.

## For more information

To learn more about how IBM's life science regulatory management capabilities can optimize your infrastructure and enhance your efficiency and compliance please contact [GlobalRegulatoryManagement@us.ibm.com](mailto:GlobalRegulatoryManagement@us.ibm.com).



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Global Technology Services  
Route 100  
Somers, NY 10589

Produced in the United States of America  
January 2015

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