

## Toolkit for Office 365 Governance

### **Establish and Maintain Oversight of Your GxP Content in the Cloud**

Governance covers a wide range of controls related to the implementation, operational use, and administration of GxP computer systems. When using cloud services like Office 365 to manage GxP content, governance includes the sharing of responsibilities between Microsoft and the regulated customer. Over time, evolving business and technical needs, and growing operational requirements add to the demand for regulated customers to have a robust governance plan in place.


With these challenges in mind, Montrium has developed a comprehensive Governance Toolkit to help life science teams securely manage their GxP data in Office 365 and demonstrate compliance. The Toolkit defines roles and responsibilities that impact how your business divisions and IT teams cooperate with Microsoft to achieve business goals.


#### **An Experienced Consulting Team**


Montrium's Professional Services team has developed, applied, and optimized our Toolkit to implement technical and procedural controls associated with hosting GxP content in the cloud. Leveraging years of experience with the Office 365 platform, our value-added governance approach aligns with industry best practices to focus on quality and risk management. We are here to help you establish governance and maintain oversight while still reaping the added benefits of moving to the cloud.


# Building a Robust Governance Plan


The Governance Toolkit provides the framework to develop a comprehensive governance plan. Appendices of the plan will help you and your team establish the following procedures:


 **Logical Security & User Access Management** Aligned with industry best practices, we help to prevent unauthorized system access with defined controls for account creation, account withdrawal, as well as user access and permission management.


 **Administration and Maintenance** Tasks are outlined to ensure that sites are maintained in a controlled manner and a schedule is implemented for routine monitoring of Office 365 service capabilities and adherence to service agreements.


 **Change & Configuration Management** A process for monitoring platform updates will be established as well as a framework for regression testing. Services can also be provided to help with your internal change management process.

 **Incident Management** A framework will be defined for security incident handling and escalation within the organization and to Microsoft, this ensures incidents are duly assessed and resolved.

 **Data Governance** To address data integrity concerns, controls are put in place for data classification, data retention, and archival of records. Internal processes are defined to support the use of technical features compatible with your business needs for protecting data.

 **Training Management** Defined training programs are key to provide the necessary knowledge on how to use Office 365 services in a way that suits your business and users' needs to both improve productivity while remaining compliant.

 **Data Backup & Recovery** To mitigate any risks to data, our Toolkit will address the backup and restoration of historical versions of records, the recovery of deleted files, and the restoration of a site from backups.

 **Vendor Management** We help you define a process that ensures Microsoft is assessed initially, and through periodic re-evaluation, for continued assurance of compliance. Please visit our Vendor Assessment Toolkit for more information on how to assess Microsoft.