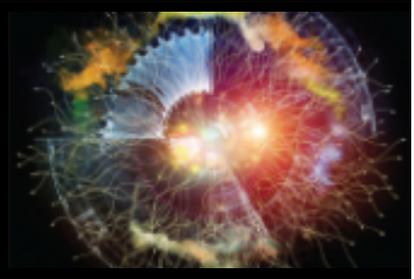


Modernizing Compliance What automation can do for Regulatory Affairs



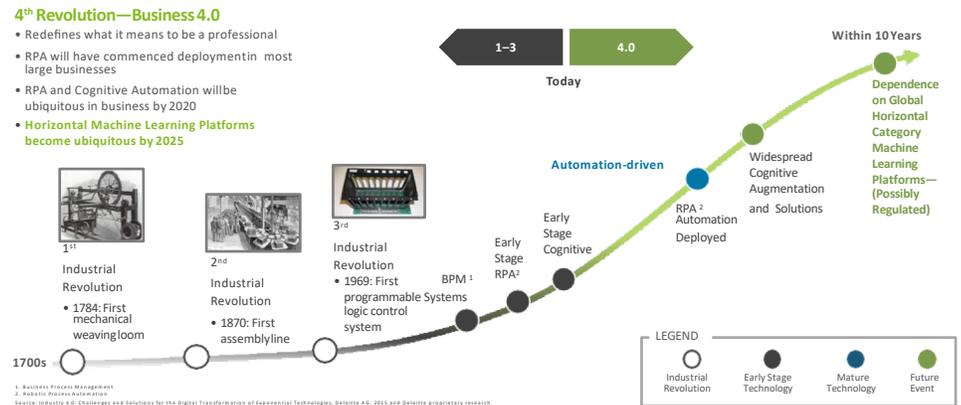
As the world's number one risk advisory organization, Deloitte Risk and Financial Advisory understands the imperatives of helping companies drive the technological revolution while remaining compliant.

Modernizing compliance

A major step toward embracing the 4th revolution within the regulatory space will be for companies to modernize their compliance programs. Deloitte Risk and Financial Advisory has developed a strategy utilizing automation technologies, including RPA and cognitive intelligence, to streamline these processes. These automation solutions are designed to help companies simplify, centralize, standardize, automate, and enhance their processes.

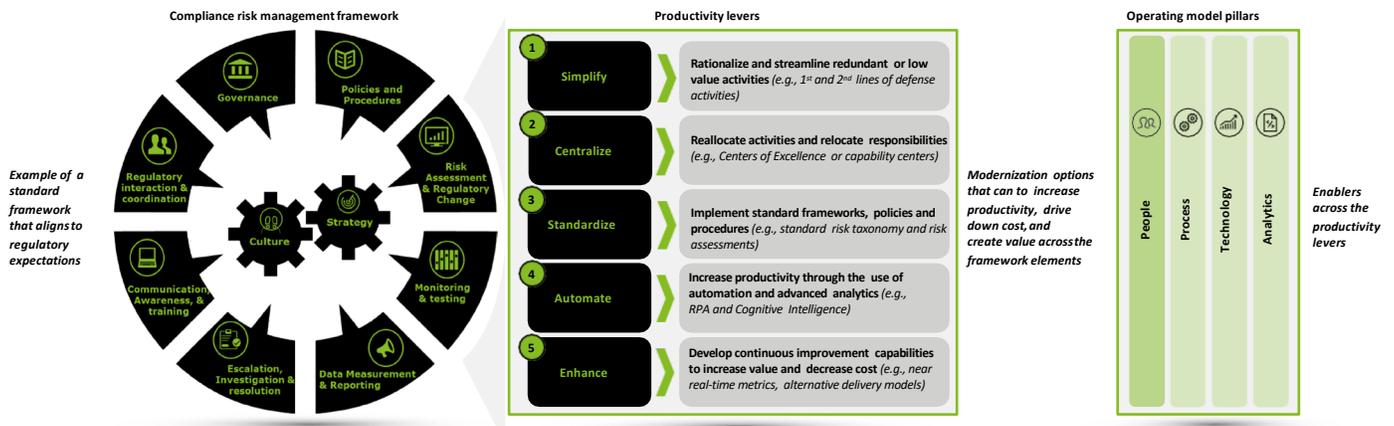
Embracing the 4th Industrial Revolution

We are at the beginning of the 4th Industrial Revolution, which is characterized by a fusion of technologies that are blurring the lines between the physical, digital, and biological spheres. This is already impacting all aspects of our lives (e.g., smart phones) and is expected to impact Regulatory Affairs by dramatically changing the requirements for regulatory professionals in the future. The operational aspect will become more and more automated, starting with robotic process automation (RPA) and leading to cognitive automation and artificial intelligence.

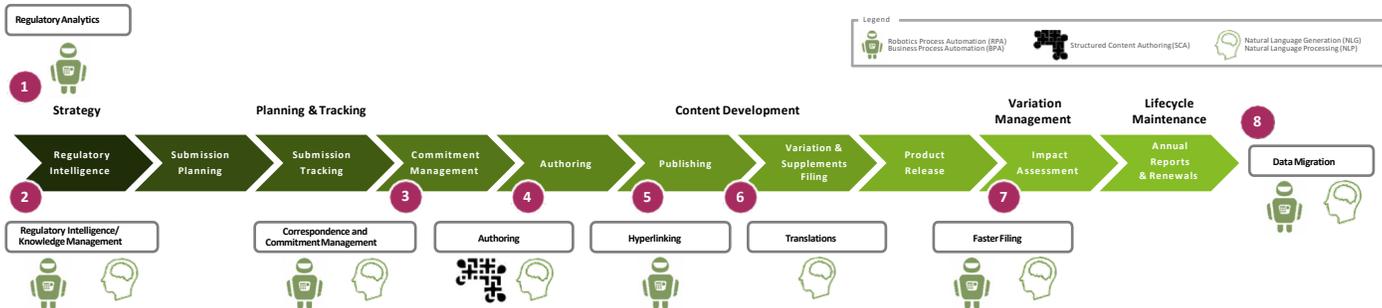
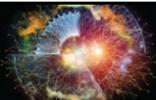


Modernizing compliance overview | Transforming compliance culture

The concept of Modernizing Compliance focuses on pulling productivity levers across components primed for modernization to drive the integration of risk and compliance with business strategy and deliver value across the enterprise



Applications | Where does automation fit?



Use Cases | Scenarios Specific to Regulatory Affairs

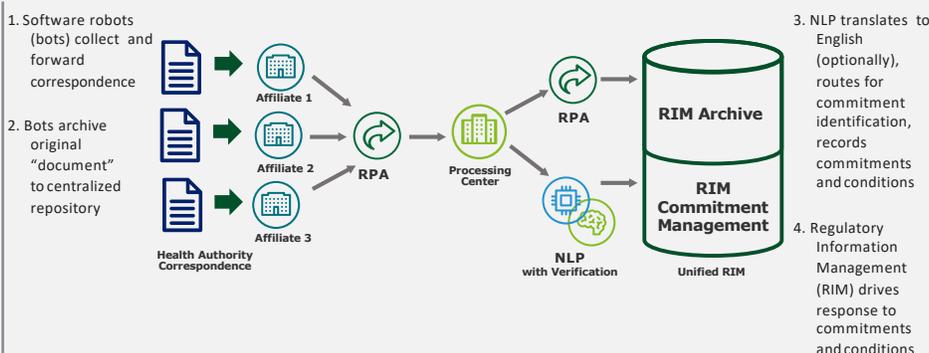
The topics below demonstrate where and how modernizing compliance can be implemented throughout the Regulatory Affairs framework

Use Case 1 | How can correspondence/commitment management be optimized?

Current challenges

- Largely manual, time-consuming work
- Inconsistent, and prone to human error and other regulatory compliance risks
- Little or no visibility to existing data or information
- Uncoordinated commitments and information places significant burden on global regulatory and manufacturing teams, sub-optimizing processes

Future state overview



Potential benefits

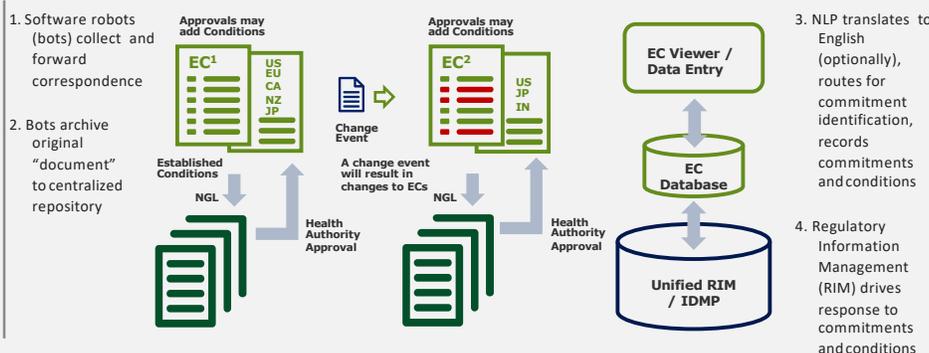
- Global visibility and more efficient use of resources
- Greater compliance with commitments met in a timely and accurate manner
- Enhanced speed through near real-time storing, routing, capture & recording

Use Case 2 | What does intelligent submission & variation management look like?

Current challenges

- Specifications and conditions of manufacture are buried in pdf documents
- Changes to specifications are embedded in dossier and hard to identify
- Managing multiple flavors (sets of specifications) is challenging given evolving approval status

Future state overview



Potential benefits

- Easier 'flavor management'
- Rapid access to clearly communicated sets of ECs
- 'Right-product/right-country product release
- Simplified IDMP compliance
- Streamlined, precise communication between regulatory and manufacturing

Deloitte Risk and Financial Advisory has created an automated global market-based risk assessment process, an automated 340B Duplicate Discount identification, and an automated analysis for open payments data for commercial strategy and compliance monitoring for large global pharmaceutical manufacturers.

Benefits | What benefit can implementing modernizing compliance capabilities provide your regulatory organization?

- Increased efficiency**
Manual, repetitive tasks related to regulatory reviews, documentation, and submissions can be completed via bots with oversight from regulatory professionals to enable more time for strategic activities, development of new competencies, and better use of resources
- Improved end-to-end visibility**
Implementing proactive and predictive capabilities into the regulatory framework could decrease cost of compliance while enabling transformative change
- Reduced cost**
Incorporating automated processes to support everyday activities could decrease labor and time devoted to regulatory lifecycle management
- Better preparedness**
As the 4th industrial revolution approaches full force, your regulatory lifecycle management can be equipped with the right tools for a smooth transition into the workforce of the future

Let's talk

Oliver Steck
Principal
Deloitte Risk and Financial Advisory
Deloitte & Touche LLP
Tel: +1 305 302 2655
Email: osteck@deloitte.com

About Deloitte
As used in this document, "Deloitte Risk and Financial Advisory" means Deloitte & Touche LLP, which provides audit and risk advisory services; Deloitte Financial Advisory Services LLP, which provides forensic, dispute, and other consulting services; and its affiliate, Deloitte Transactions and Business Analytics LLP, which provides a wide range of advisory and analytics services. These entities are separate subsidiaries of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of our legal structure. Certain services may not be available to attest clients under the rules and regulations of public accounting.

This publication contains general information only and Deloitte is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This publication is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor.

Deloitte shall not be responsible for any loss sustained by any person who relies on this publication.
Copyright © 2018 Deloitte Development LLC. All rights reserved.