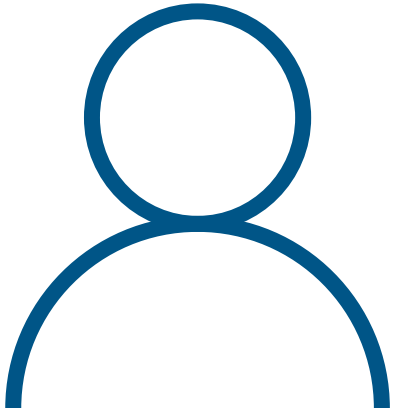
Global Regulatory Requirements for Medical Devices

Design for Registration

Michael King
Senior Director of Product & Strategy, IQVIA

> How quickly can we launch this product in all global markets?



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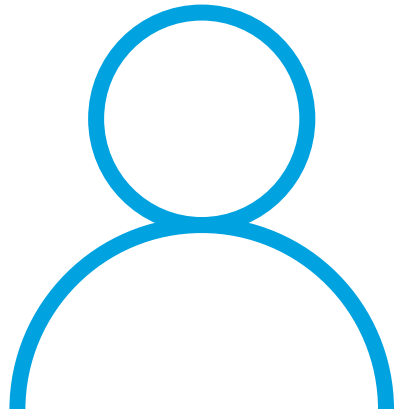

Reg Affairs Professional

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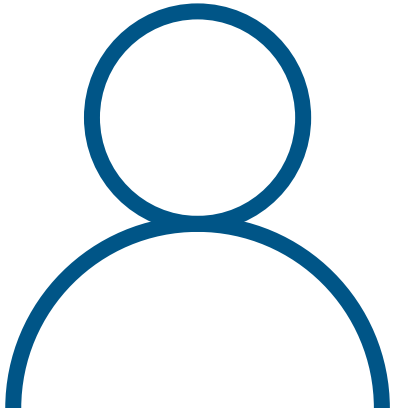

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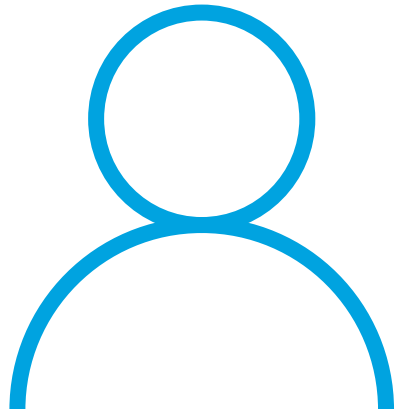

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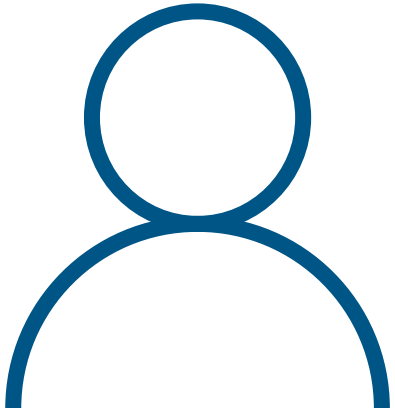

We have customers waiting! Why is this taking so long?

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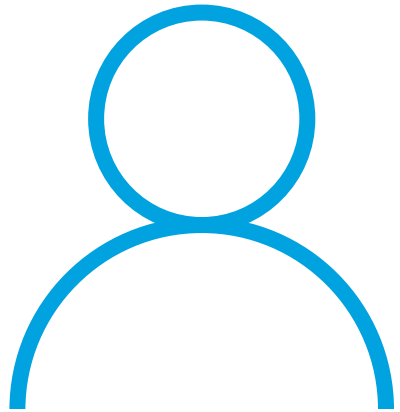

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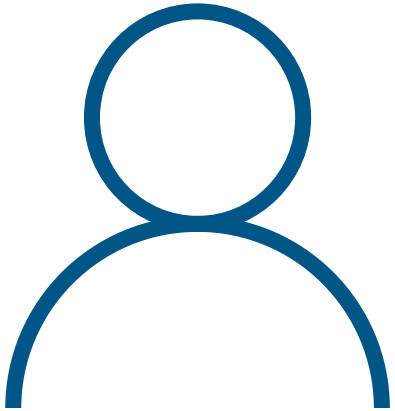

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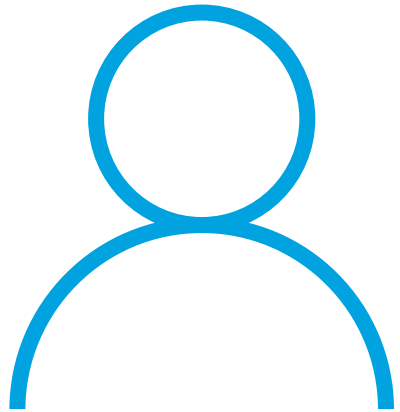
It's complicated…



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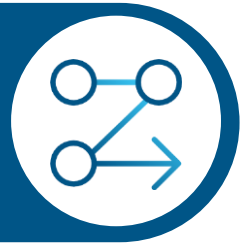
Overview

Considerations for Global Product launches
Why “It depends” and “It’s Complicated”

Design for Registration
Bringing transparent and conscious decision making to global product launches



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Supporting the professional activities of Regulatory Affairs

Considerations for Global Product Launches

Five Go-To-Market Challenges for Regulatory Professionals

1. Global Drivers to Regulation

Patient Safety, Politics and Economics are key influencers to regulation

Patient Safety

Politics

Economics

Industry Specific

- *Total Joint Reclassification (2005/50/EC) - 2005*
- *Total hip, knee & shoulder "upclassified" from IIb to III*
- *Elbows remained IIb*

Individual Country

- *Brexit – End Jan 2020*
- *Swissexit – End May 2021*

Inter-Country Dynamics

- *Mutual Recognition Agreements (or not)*
- *Slower review timelines during political turmoil*

2. Global Regulatory Variation

Global complexity in regulation continues to advance

US and EU approvals are not universally accepted

Many countries have additional documentation reviews

Some countries require additional technical, toxicological and clinical activities

3. Product Specific Requirements

Identifying what data is required for product registration is key to a successful global launch

Different product types are subject to different global and local standards

Local standards can vary with globally accepted standards

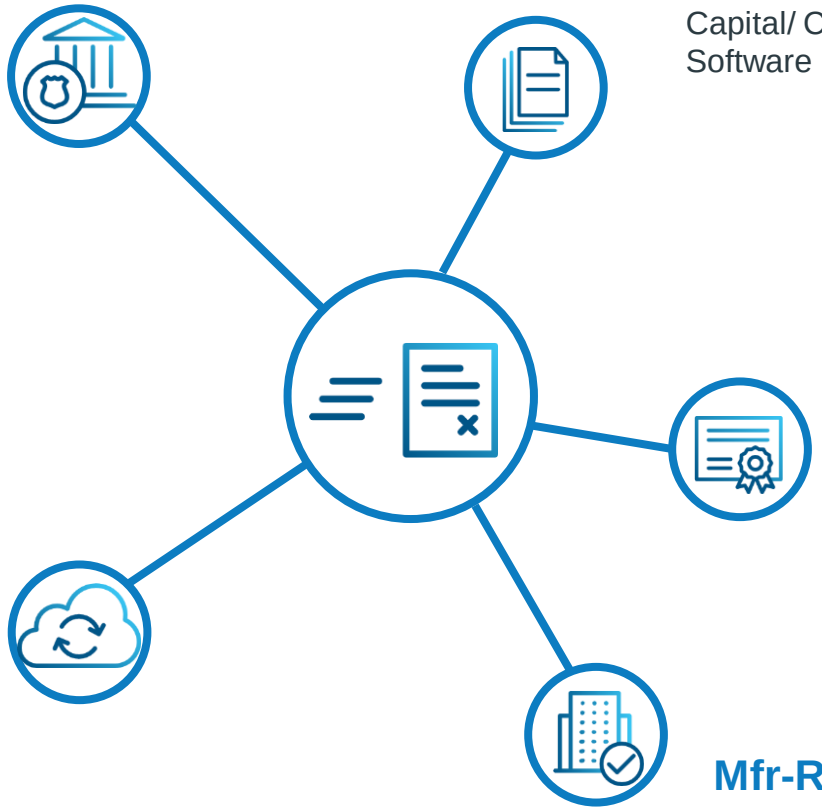
A MD isn't always a MD (sometimes it is a NMD or a Pharma product)

4. Regulatory Submission Variation

Submission strategy and registration dossier content has an impact on product launch timelines

Legal Entity
Company vs Agency vs Dealer(s)

System
Capital/ Consumable(s)/ Software in one submission



Product Type
Capital/ Consumable(s)/ Software in independent submissions

New vs Re-regn.
Risk vs Reward

Mfr-Risk-Intended Use
Capital/ Consumable(s)/ Software in many independent submissions

Global variation in submission strategy and registration dossier content exists

The choice (or mandate) of an in country legal entity / in country importer affects the registration pathway

5. Global Registration Approval Timelines

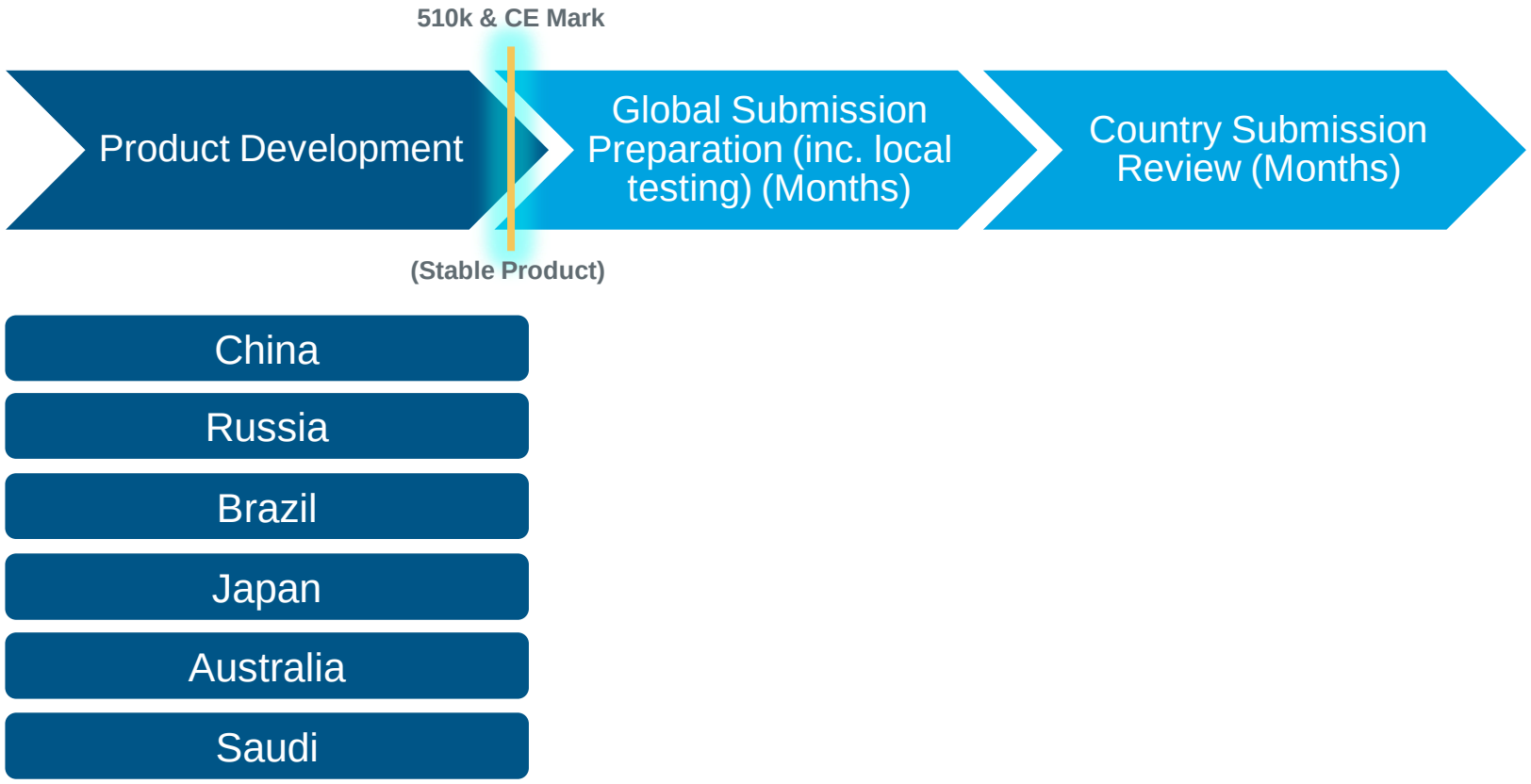
Product testing requirements and documentation availability drive workflow dependencies

Often required that a stable product is launched in the finished goods country of manufacture before a country's own registration process starts

Lengthy timelines in countries that require additional toxicological, technical and clinical testing

5. Global Registration Approval Timelines

Product testing requirements and documentation availability drive workflow dependencies



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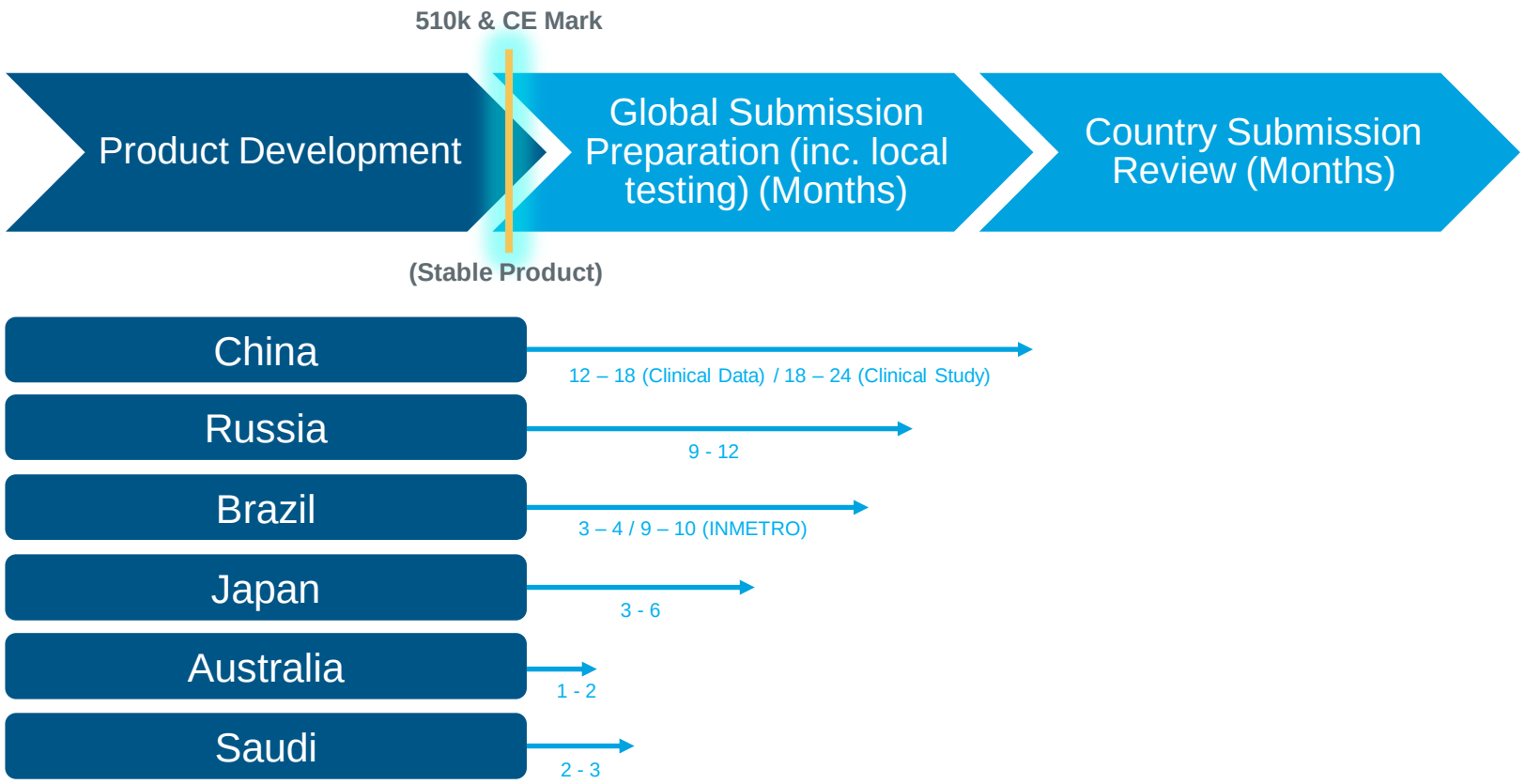

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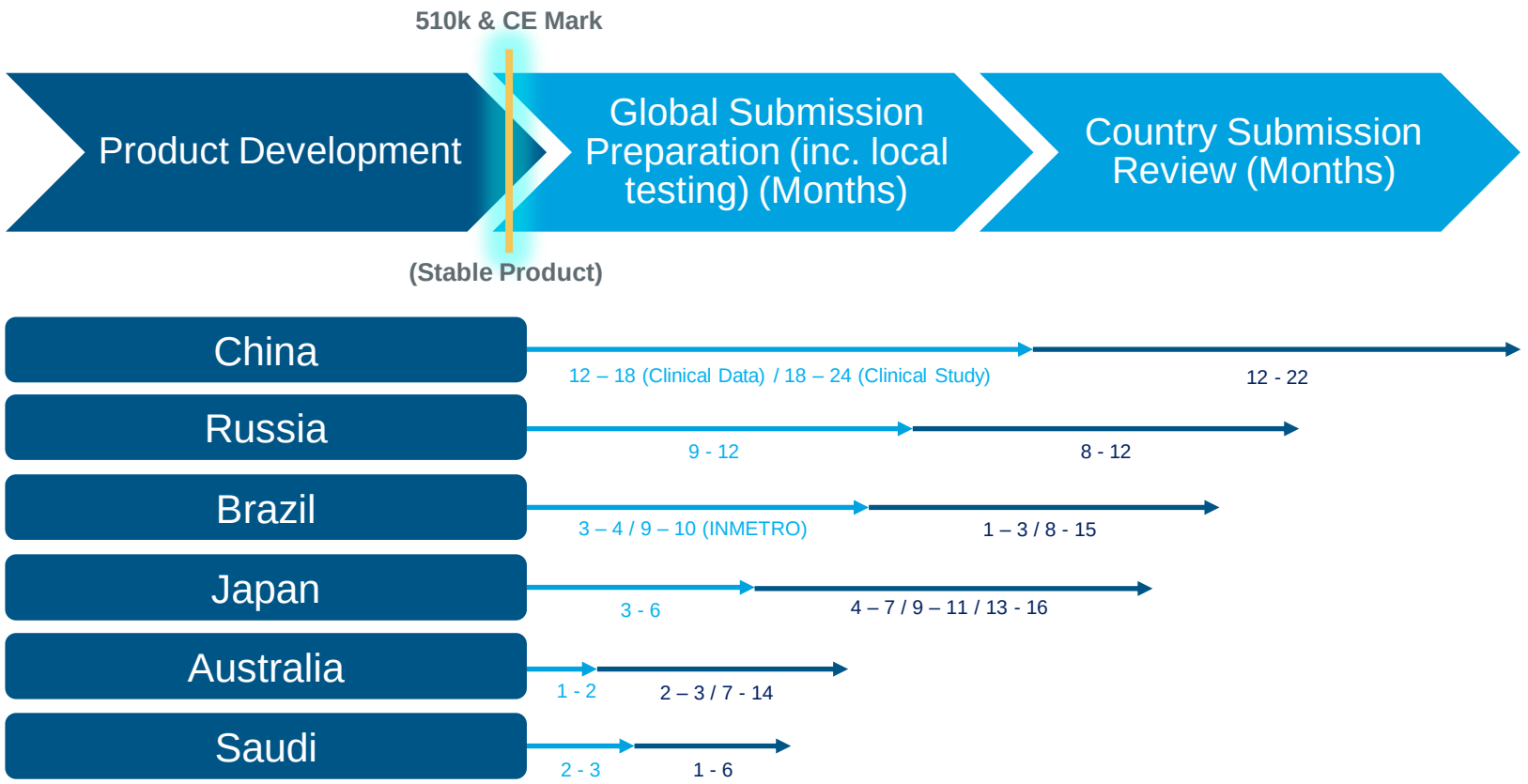

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Design for Registration

Plan-Do-Check-Act

Design for Registration

Global product launches require a global approach for requirements, resources and timelines

Scope **Global Inputs** **Communication** **Embrace Reality** **Raise the Vision**

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Scope | **Global Inputs** | **Communication** | **Embrace Reality** | **Raise the Vision**

Begin with the end in mind:

- Target countries
- Launch sequence
- Registration pathway

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- Clinical
- Product toxicological testing
- Product technical testing
- Local standards
- Local documentation requirements

Communication

Embrace Reality

Raise the Vision

IQVIA TECHNOLOGIES

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- Launch scope
- Project changes
- Critical path
- Include global regulatory early in the plan

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- 3rd party agency
- Dealer
- Commercial
- Operations
- Regulatory & Quality

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Adjust global launch expectations:

- Traditional launch nominally 2-3 years in US/ EU
- Global launch circa 3-5+ years
- Impacts retainment of resources throughout project lifecycle

IQVIA TECHNOLOGIES

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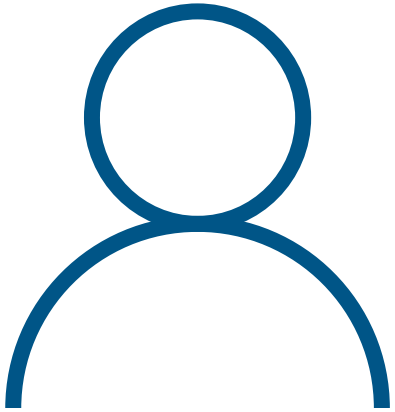

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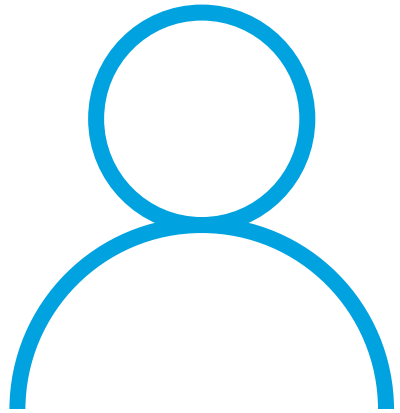

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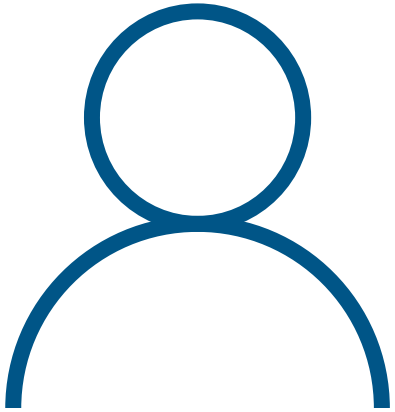

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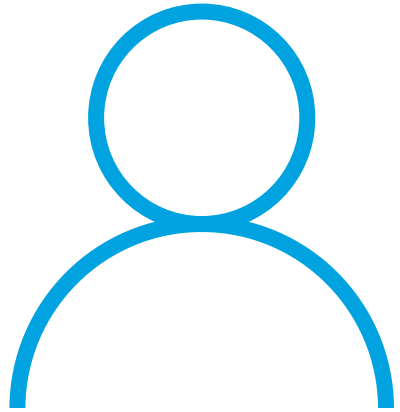

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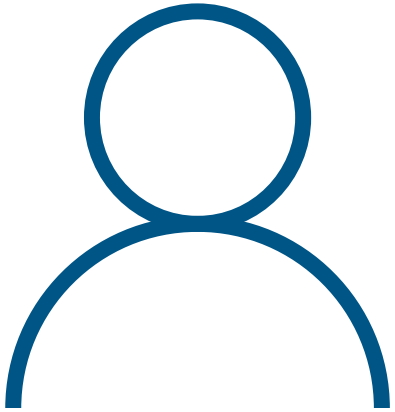

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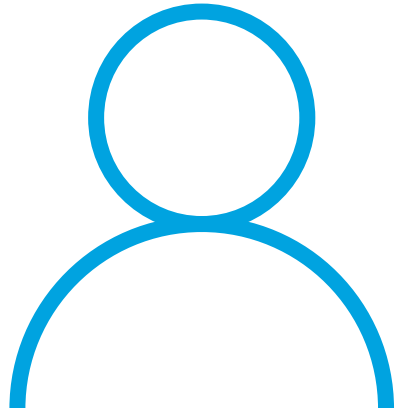

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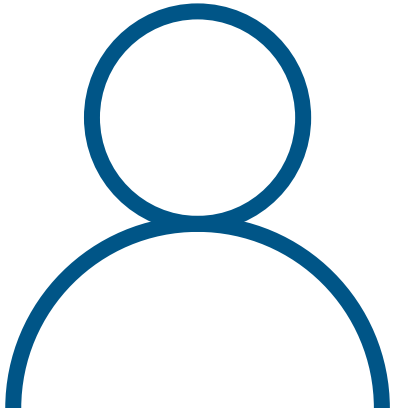

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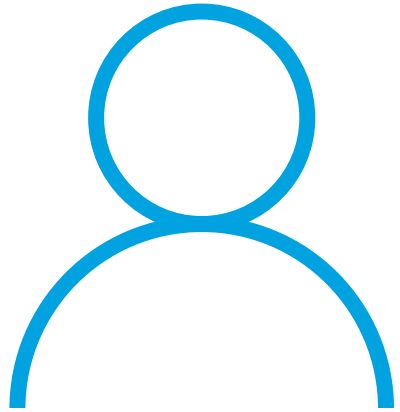


Reg Affairs Professional

Connected Intelligence™

Supporting Regulatory Professionals in their daily activities

Our Industry is facing unprecedented regulatory complexity

$9B+ industry-wide spend growing at an unsustainable rate

150% **Increase in Regulatory Mandates in the last 5 years[1]**

Every 22 Minutes
New or changed regulation somewhere in the world[4]

100% Growth in Adverse Events and Product Technical Complaints during 2021 vs. 20% historically

Global CEOs
Consider industry regulations a top disruptive business trend[2]

Nearly 500,000

Global Regulations and Reference Documents
Devices | IVDs | Drugs | Biologics

> 55% of critical findings
in MHRA audits came from Signal Detection and Risk Management Deficiencies

22,000 New Regulations/Year[3]

- How can I keep up?
- How do I not miss something?
- How do I understand country-specifics?

Non-English Speaking

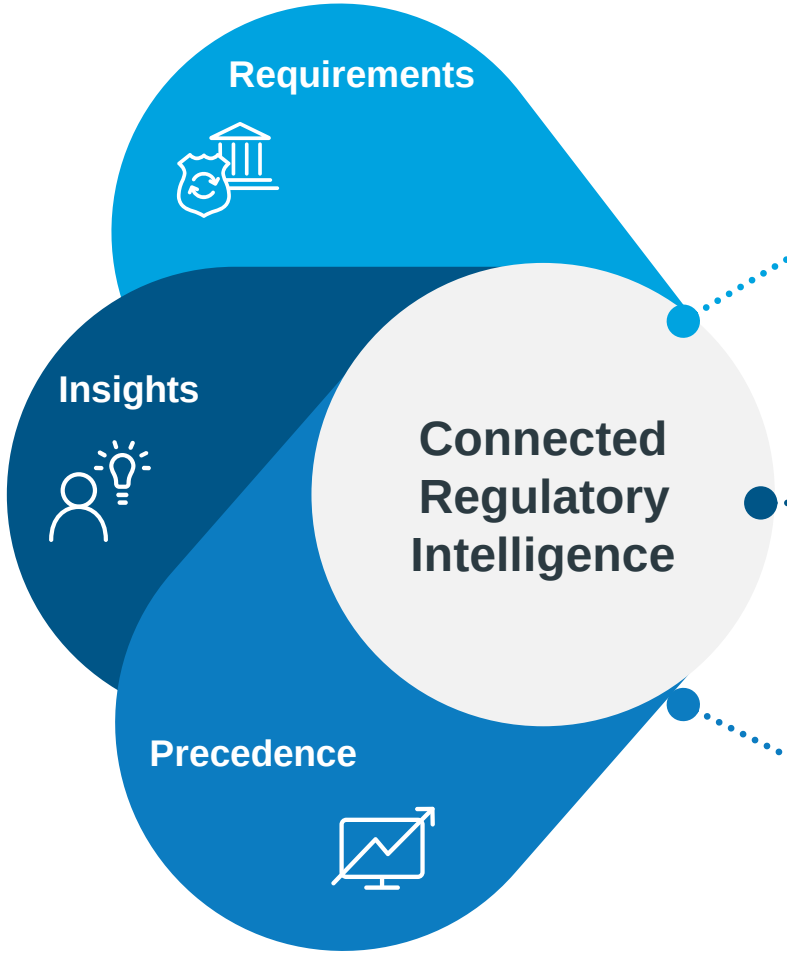
Over 160 countries, regions and authorized organizations

$200M
Spent by medical device on remediating compliance/quality issues (WSJ)

1 IQVIA Regulatory Intelligence May 2022
2 PwC, 21st Annual Global CEO Survey
3 IQVIA Regulatory Intelligence May 2022
4 IQVIA Regulatory Intelligence May 2022

IQVIA TECHNOLOGIES

What is Connected Regulatory Intelligence?



Requirements (Curated data about Health Authority requests)
- Machine readable
- By regulatory activity
- Product type specific

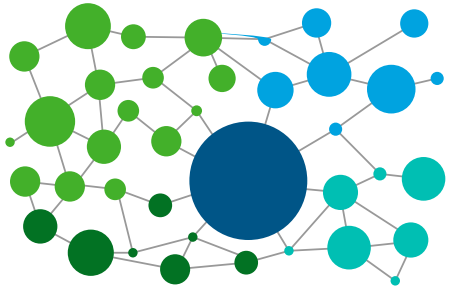
Insights (Client´s own interpretation)
- User edits / tribal knowledge
- QCd by data steward
- Ready for analytics and re-use

Precedence (Client´s own experience)
- Operational history
- Audit trail
- Ready for analytics and re-use

Transforming Healthcare with Connected Intelligence™

Control the controllables, automate the transactional, optimize and enhance professional activities

THE RIGHT DATA



THE RIGHT INSIGHTS

Data sourcing + Data Transformation + Insights Generation

THE RIGHT ACTIONS

- Safety
- Regulatory
- Quality

- Integration
- Automation
- Simplification

THE RIGHT TIME

*Regulatory Intelligence operates across the safety, Regulatory & Quality space

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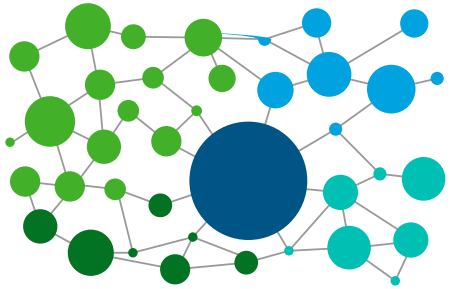

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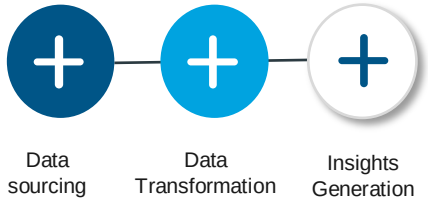

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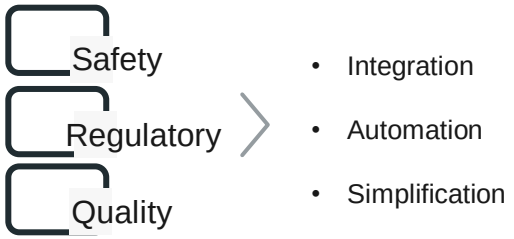

- Integration
- Automation
- Simplification

THE RIGHT TIME

Regulatory Intelligence* & Reference/ Operational Data:

- *Adverse Events*
- *Registrations*
- *CAPA*

Targeted Insights Built by and for industry professionals:

- *Signal Detection*
- *Predicate Analysis*
- *Root Cause Analysis*

Focused Actions:

- *AE Reports/ PSURs*
- *Submissions*
- *Change Control*

Exceeding Stakeholder Expectations:

- *Initial, final & follow ups*
- *Submissions & HA response*
- *Product impact assessment*

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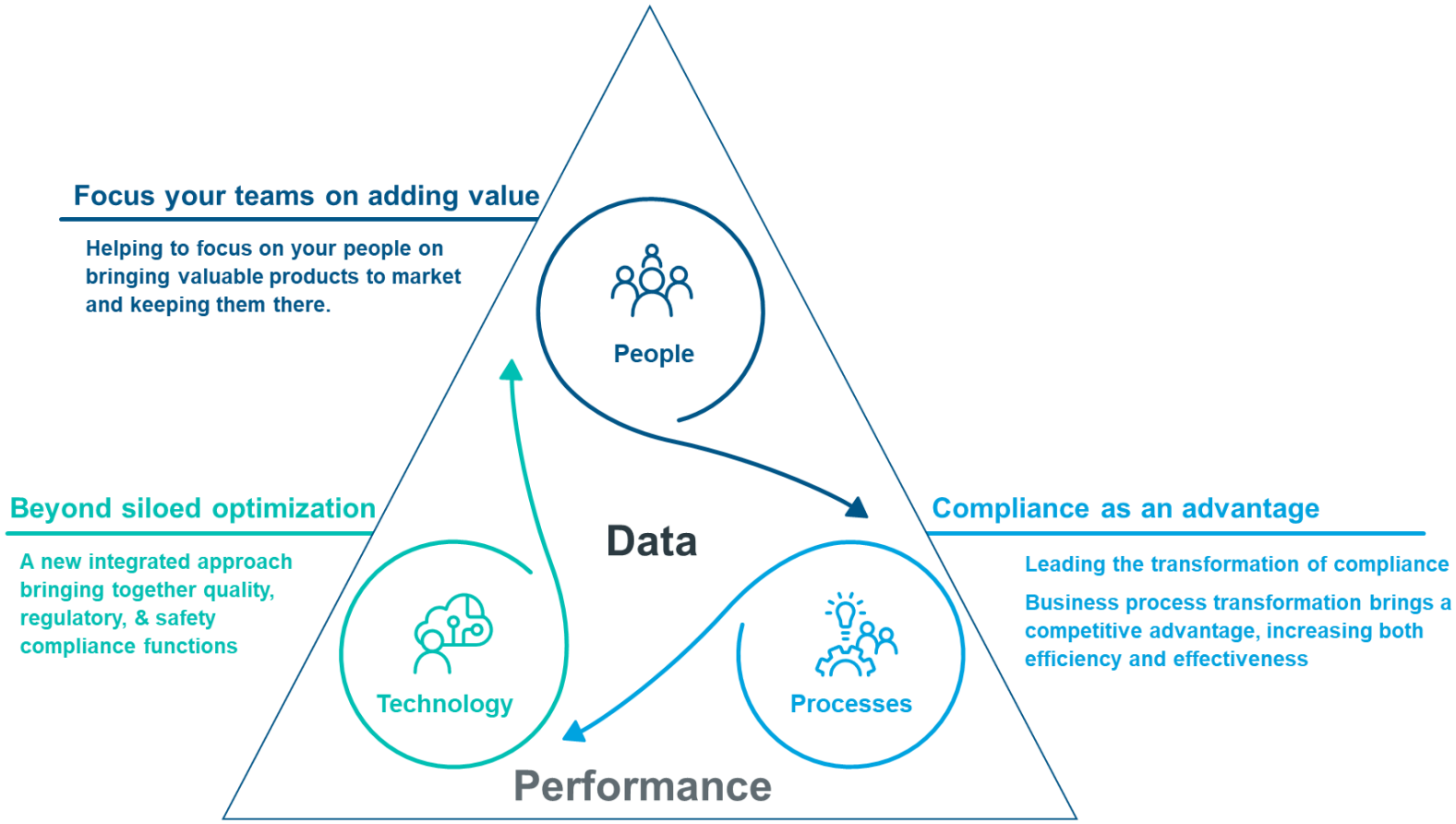
IQVIA's Approach to Technology

People, Processes, Technology – driven by high-quality data



Focused industry professionals supported by clear processes and enabled by leading technology will enhance global product lifecycle activities inclusive of the go to market and post market activities

IQVIA TECHNOLOGIES

Closing Comments

Summary

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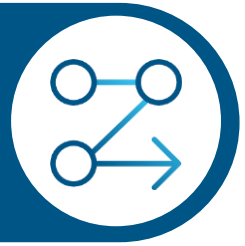

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Any Questions?