Dot Compliance

How to Implement Your QMS in One Month

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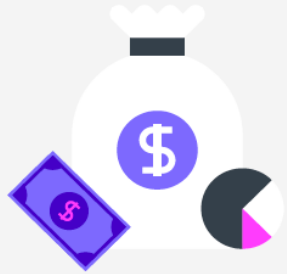
Agenda

- Myths vs. Reality
- The Dangers of Conventional QMS
- Shattering the Status Quo
- 30-day QMS Adoption
- Building a Future Ready Strategy

It’s 2022: Should it still take months or years to implement QMS solutions?

Myths vs. Reality

The days of spending months and years implementing a QMS are over!



MYTH

As a life science company, you need a costly and complex quality management system (QMS) that cripples you financially, takes months to configure and implement, and continuously surprises you with hidden fees for updates, upgrades and validation.

REALITY

Within weeks you can be up and running with a ready to use, cloud-based QMS that is preconfigured based on industry best practices to support the quality and compliance processes you need when you need them.

POLL QUESTION # 1

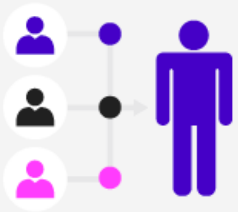
How are you currently managing your quality and compliance processes?

1. Cloud based QMS
2. On-prem QMS
3. Homegrown solution
4. Paper based

Typical conventional approach

Challenges of a conventional QMS

- Waterfall in nature
- Overly customized
- Time-consuming
- Costly to implement and maintain
- Resource intensive
- Typically, 6 to 12+ months in duration
- Technical challenges often take on a life of their own
- Validation becomes the focus
- Regulations change
- Knowledge becomes siloed



The QMS provider asks the customer for their requirements, gathers that information, customizes/configures their standard solution, and presents it to the customer, all of which results in costly solution delivery and professional services costs.

If the customer decides they want a different configuration, the QMS provider must go back to the drawing board, conduct a redesign, and present it again and again until it is right. With each round adding additional time and expense.

What many life science companies don't know is that each time a change is made to a blank canvas QMS configuration, the provider must re-validate it. These changes often result in months and months of professional services - raising costs significantly.

So, what's the alternative?

A QMS paradigm shift

Ready to Use

Comprehensive ready-to-use QMS solutions. Pre-configured and pre-validated system based on best practice processes provided with Sample SOPs and KPIs.

Seamless Deployment

Install quickly and get up and running within a matter of days with minimal setup required, leveraging advanced data migration capabilities

One-Stop Shop

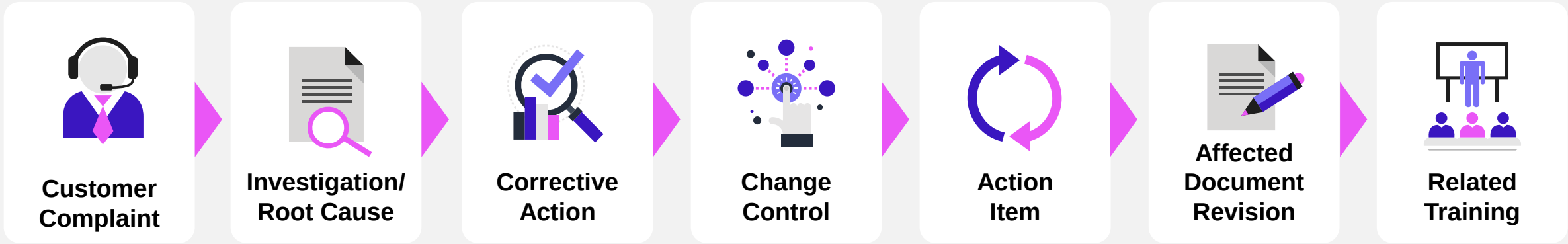
A comprehensive set of ready-to-use modules. A replacement for multiple systems: QMS, DMS, LMS, Electronic forms, SQM, Audit Management, EBR, PLM, ALM/Design Control, LIMS, ELN, RA & RIM, CTMS, Maintenance, Calibration, ITC

Industry's most cost-effective eQMS solution for the Midmarket

Eliminate expensive and time-consuming customization and solution delivery costs. Purposely built to scale based on your needs.

End-to-end visibility across entire ecosystem

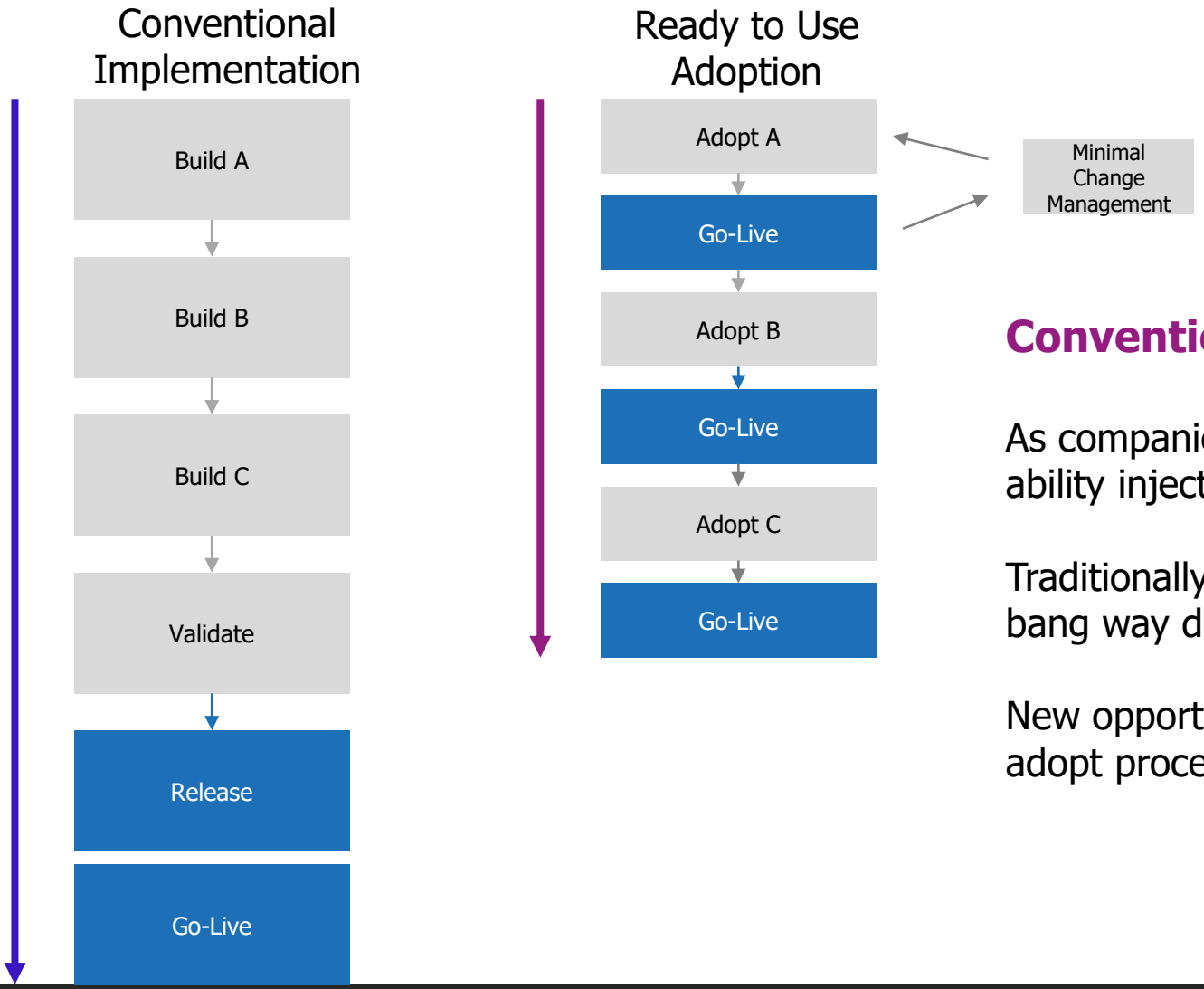
- You can easily navigate between processes and associated data, related documentation and drill down to the sources of each process or quality event.
- Based on user's security permissions, they can see the full picture in **just a few clicks.**



Key attributes to look for

- **Look for a QMS with the following key attributes:**
  - Industry-standard, pre-configured and integrated, core QMS processes
  - End-to-end process visibility
  - Ability to expand beyond core quality processes
  - Built on a secure and trusted SaaS platform
  - Predefined user profiles
  - Connectors to ERP, HR, and other key systems
  - Full and transparent validation package including process PQs
  - Access to analytics and insights
  - Compliance with 21 CFR part 11, EU-Annex 11 and support ISO 9001, 13485, 14971, 27001 and other relevant GxP regulations.

Adoption versus Implementation



Conventional vs Ready To Use

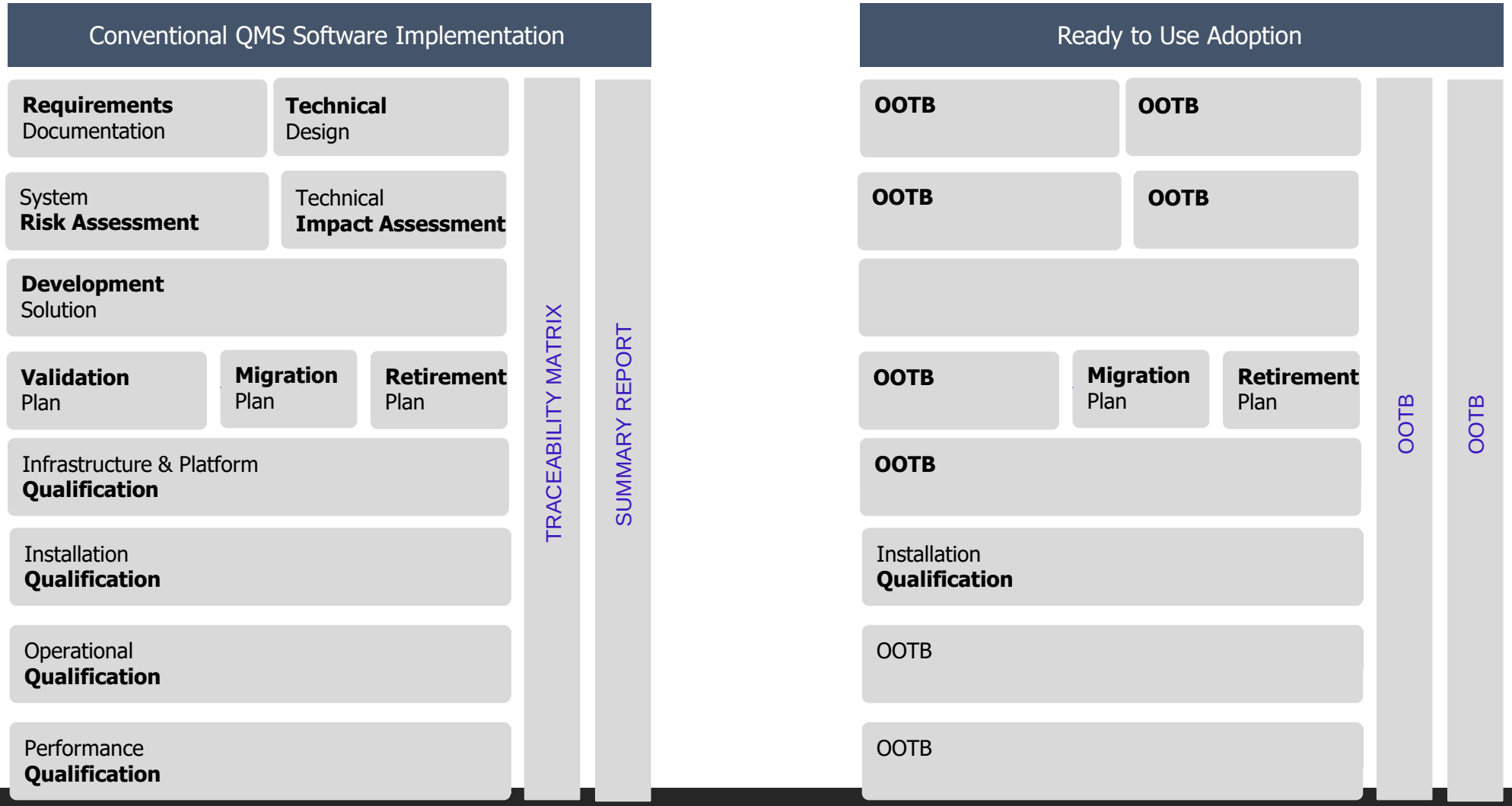
As companies adopt ready to use solutions, they gain the ability injecting agility into the process.

Traditionally, companies would release solutions in a big bang way due to dependencies between builds.

New opportunities exist with ready to use solutions to adopt processes on-the-go.

Validating a conventional QMS vs Ready to use

All SaaS are not created equal.



POLL QUESTION # 2

In regards to quality and compliance, what is the biggest challenge you are currently facing?

a. Paperwork overload

b. Lack of quality engagement

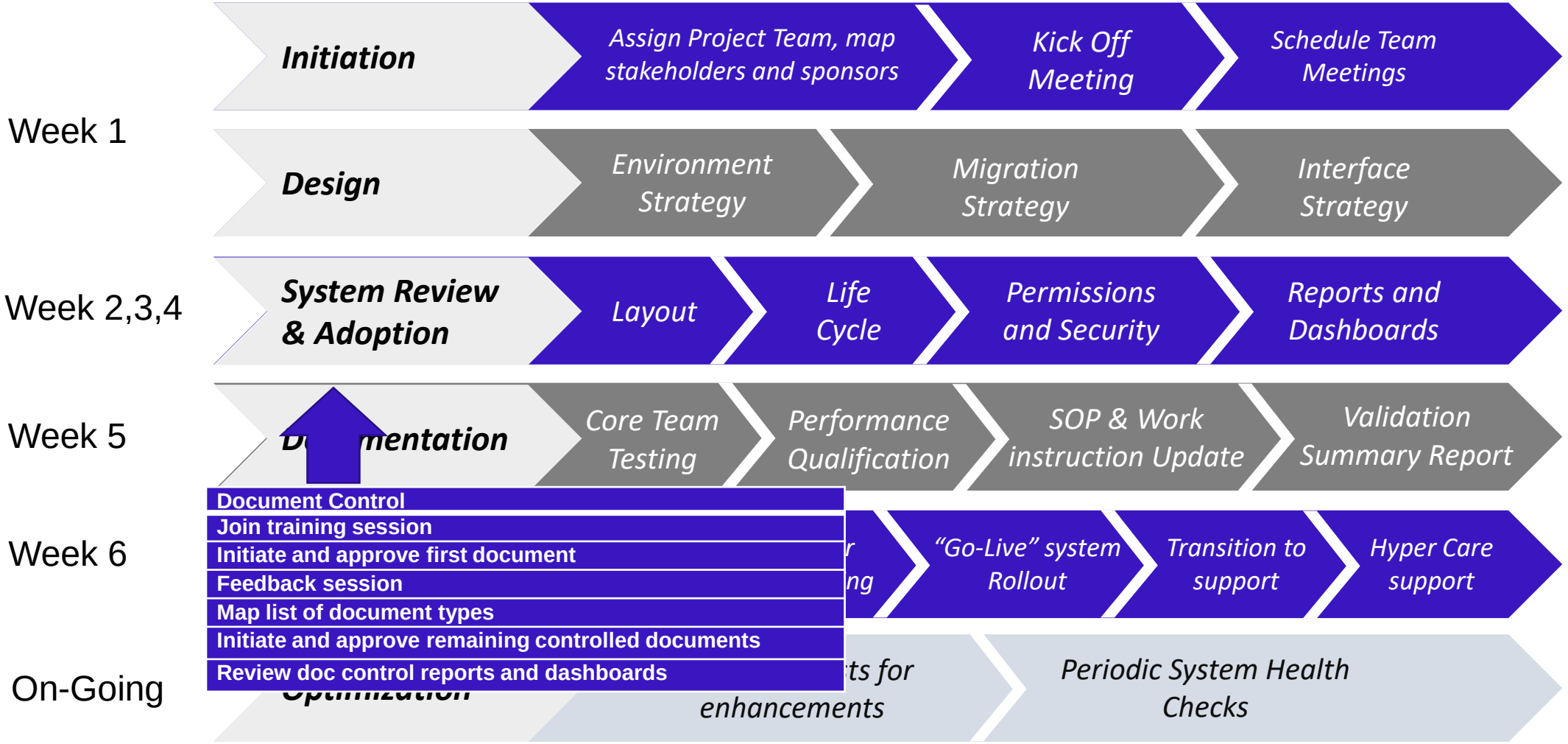
c. Disparate systems used for different processes

d. We have an upcoming audit

e. Our systems and processes need to catch up with our growth

What can a life science organization expect to happen during the adoption process?

High-level 30-Day adoption plan



Missing the Big Picture: Shortsighted Strategy

How do I ensure we build strategy that is future ready?

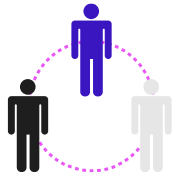
POLL QUESTION # 3

Does your organization have a digital transformation task force set up?

a. Yes

b. No

Know your barriers to change

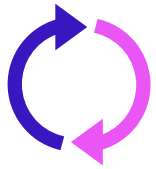


Leadership

- Lack of vision
- No commitment
- Lack of investment

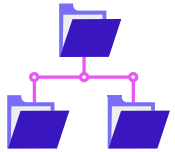
People

- Fear of change
- Lack of experience/skill gaps
- Human capital deficit



Process

- Siloed processes
- Process/Product variations



Data & Technology

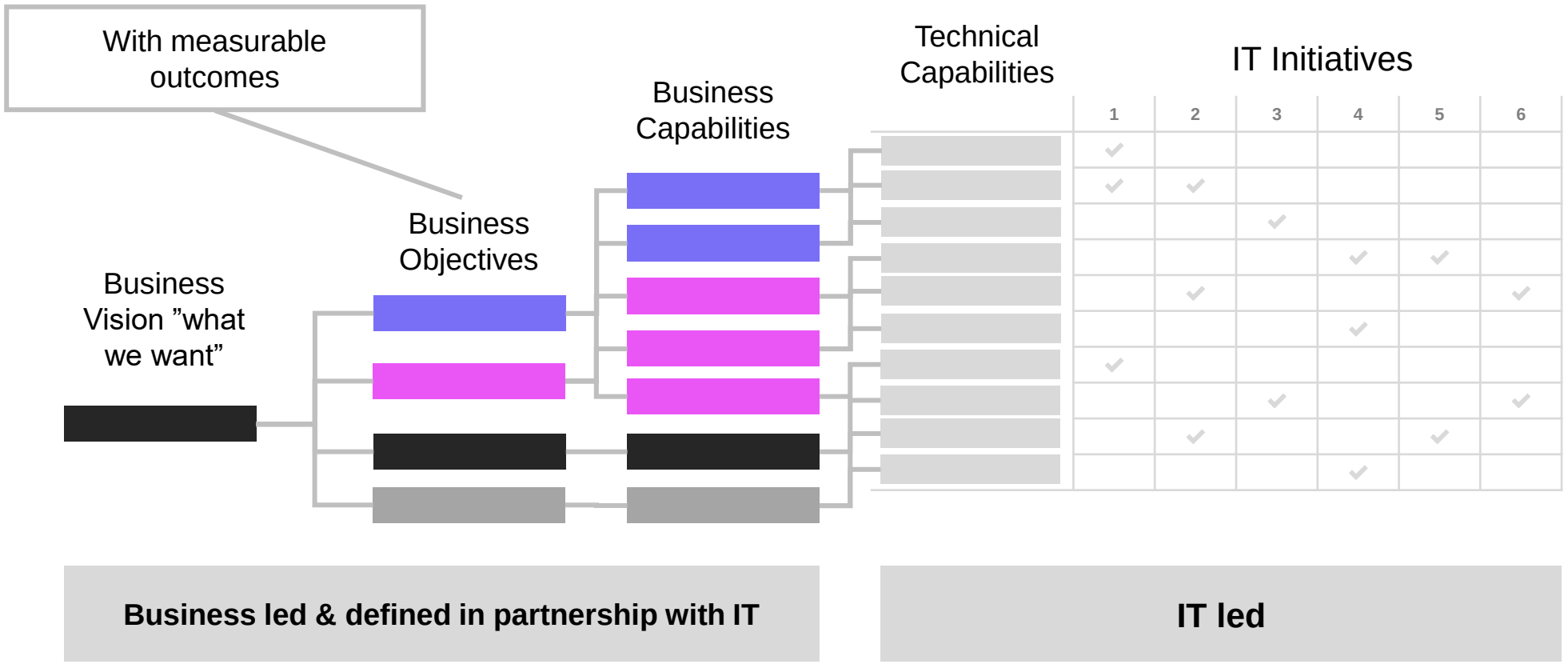
- New technology/ experience
- TCO
- Complexity
- Data volume
- Cyber security concerns

Quality & Compliance

- New regulations and guidance
- Lack of regulatory guidance on new tech
- Data integrity

Digital Priorities, Roadmaps & Initiatives

Strategy maps help to align business and IT



Overlooking the Cultural Aspects of Change

What are best practices for addressing a QMS adoption from both a business and a technical perspective?

Culture shift - IT

The Challenges Today

Overly Focused on Tech
Technically sound solution that does not meet the underlying business needs.

Lack of Buy-in
Inadequate involvement from stakeholders resulting in a lack of buy-in and ownership.

Unclear Communication
Unclear communication resulting in confusion, mixed messages about the effort, damaging organizational support and momentum.

The IT Transformation

Focus on Outcomes
Define clear lines of ownership between IT and business to illustrate how/when collaboration must occur.

Buy-in
Established formal governance roles and responsibilities to achieve the organizations vision with clear escalation paths.

Communication
Multidisciplined change agents who are passionate about the objectives and plan to communicate early and often about expectations and value to avoid resistance.

In Closing

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1. Ready to use is the way to go.
2. Start on a strategy and vision now.
3. Identify pain points or challenges with current processes and ensure the solution address those concerns.
4. Remember to stay focused on the business outcomes.
5. Technology should never be the driver.

Thank You

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Who We Are

Dot Compliance offers a holistic, innovative, end-to-end Quality and Compliance Solution powered by the **Salesforce.com** platform.

Good to Know

We are designed for fast deployment, flexibility and minimal implementation effort.

- ✓ Includes all core quality assurance processes, training, regulatory compliance, and document control
- ✓ Dot Compliance ready to use solutions helps you mitigate device manufacturing risks, while ensuring compliance with regulations such as 21 CFR Part 11, 21 CFR Part 820, GMP, ISO13485, ISO9001, and others
- ✓ Ensures your organization and outsourced suppliers get the required visibility in real-time from early product development – design history files (DHF) and device master records (DMR), manufacturing – to post-market surveillance.