

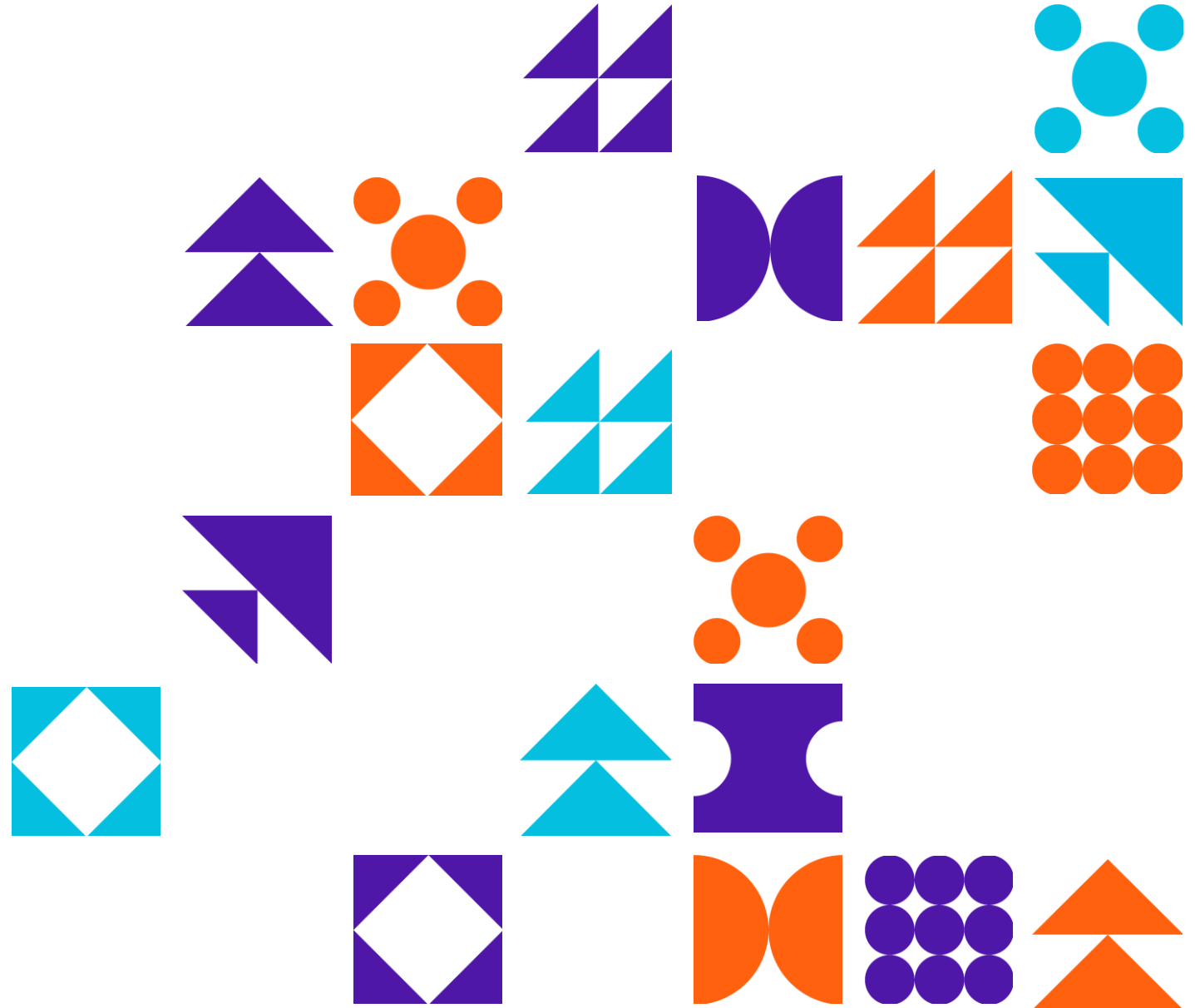
Navigating Compliance

Effective Project Management in
Regulated Industries

Girish Srinivasan

PDD 2024 | PMI-OC

02 24 2024



ABOUT ME



Work Experience

- **Current: Amazon**
- **Health Care Life Sciences (HCLS)**
Edwards Lifesciences, Boston Scientific, Sanofi, BCBS, J&J
- **Big 4 Management Consulting**
Deloitte, KPMG
- **Start-ups and Freelance**

Girish Srinivasan



Education

- *Masters in Electronics and Telecommunications Engineering (M.Tech)*
- *Bachelors in Electronics Engineering (B.E.)*



Certifications

- *Program Management Professional (PgMP)*
- *Project Management Professional (PMP)*
- *Certified Scrum Master (CSM)*
- *Certified Scrum Product Owner (CSPO)*



PMI Volunteer

- **Global PgMP Panelist:** *Trained to review and grade PgMP applications*
- **PMI-OC PMO:** *Support PMI-OC Program Management Office (PMO)*
- **PMI-OC Mentoring:** *Mentor aspiring project management candidates*

Agenda

Definition and Need for Regulation

Industry Use Cases

Challenges and Recommendations

Resources: Tools and Templates

What is Regulatory Compliance?



Compliance

Conforming to a rule, such as a specification, policy, standard or law.



Regulation

a rule or directive made and maintained by an authority.



Regulatory Compliance

the process of complying with applicable laws, regulations, and the other rules issued by governments and regulatory bodies.

Corporate compliance is different from regulatory compliance

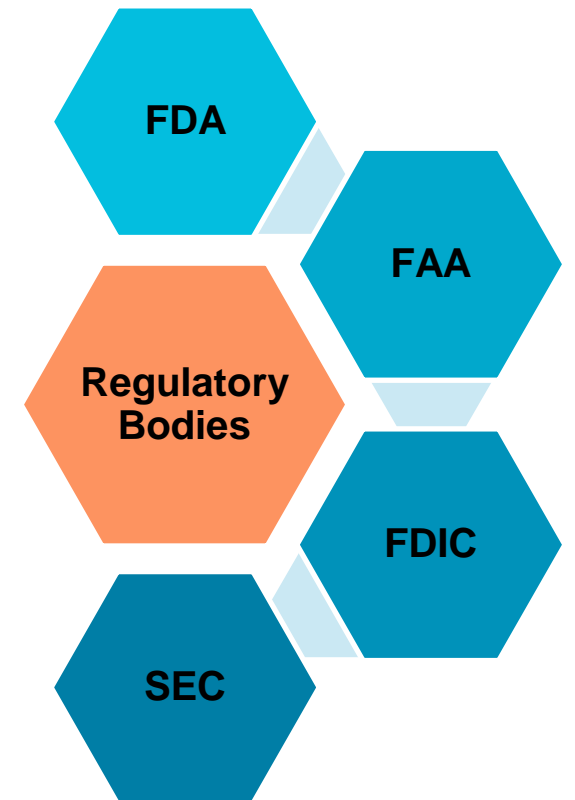
- Regulatory compliance involves following legal mandates and legislation as directed by governing bodies.
- Corporate compliance refers to the ways in which a company adheres to its internal compliance structure.

What is a Regulated Industry?

Regulatory Agency is a governmental body that is formed by a legislature to oversee and enforce law.

Regulated industries are those with specific, government-backed bodies that have direct authority to oversee aspects of those industries.

In other words, regulated industries have stakeholders with the power of the law.



- **Regulated Agencies**
- **Legal**
- Executive Sponsor
- Steering Committee
- Program Manager
- Project Manager



Why do we need regulation?

Safeguard consumer interests

Regulated industries are subject to a plethora of rules, standards, and laws designed to safeguard consumer interests, maintain industry integrity, and promote public safety.



Improved Public Image

- Demonstrate a commitment to safe and ethical operations
- Gain a positive public image
- Increase brand value



Improved Efficiency

- Streamline procedures and processes
- Improve productivity
- Reduced cost



Reduced Risk and Liability

- Abide by laws and regulations
- Reduce the risk of penalties, fines, and other forms of liabilities



Greater Resilience

- Improve resiliency to changing regulations
- Enhance business continuity

Cost of Non Compliance

This energy company used a variety of accounting tricks to inflate its profits and hide its debts. The stock price plunged from \$90.75 in mid-2000 to less than \$1 per share in Nov 2001.



The automobile company programmed to shut off the exhaust control equipment after emissions testing was completed and ended up paying \$32 billion in fines and settlements.



The telecom giant 'cooked the books' by recording operating expenses as investment. When it was exposed, the stocks plummeted from more than \$60 to less than \$1.



Regulatory compliance is expensive. But, regulatory non-compliance can be infinitely more expensive.

Most Regulated Industry



Health Care
Life Sciences



Finance



Aeronautical



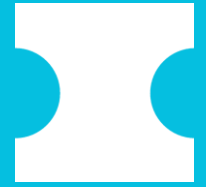
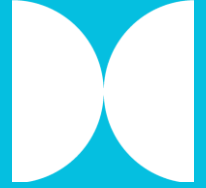
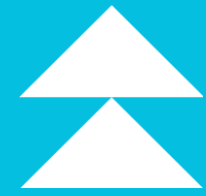
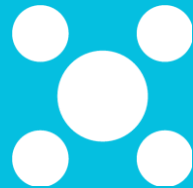
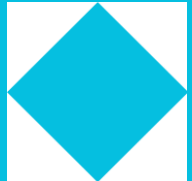
Technology



Manufacturing

The most regulated industries are those which have the deepest impact on people's lives and could cause the most potential harm.

Industry Use Cases



Use Cases

Health Care & Life Sciences (HCLS)



Technology



Use Case - HCLS

Health Care & Life Sciences (HCLS)



Technology

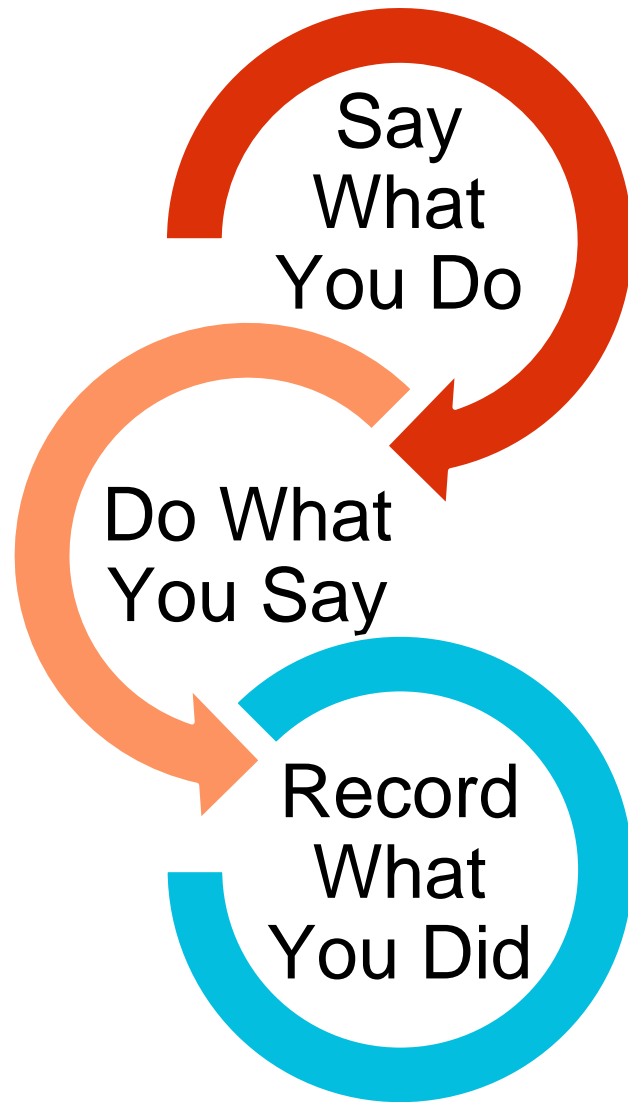


Extended Lifecycle

The average time for taking a new medication from candidate nomination to launch has been about 12 years. (Source: McKinsey)



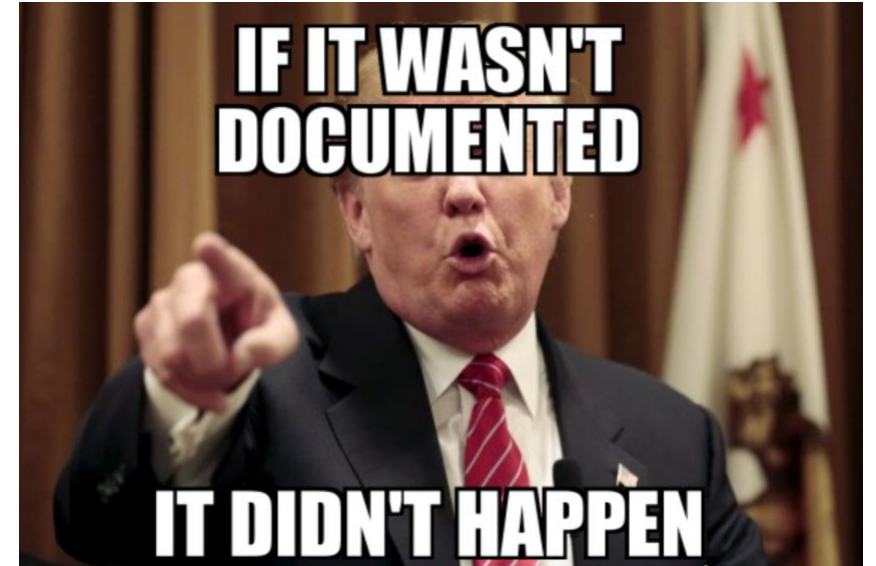
Rigorous Documentation Standards




- Document so you will consistently do the job the same way every time

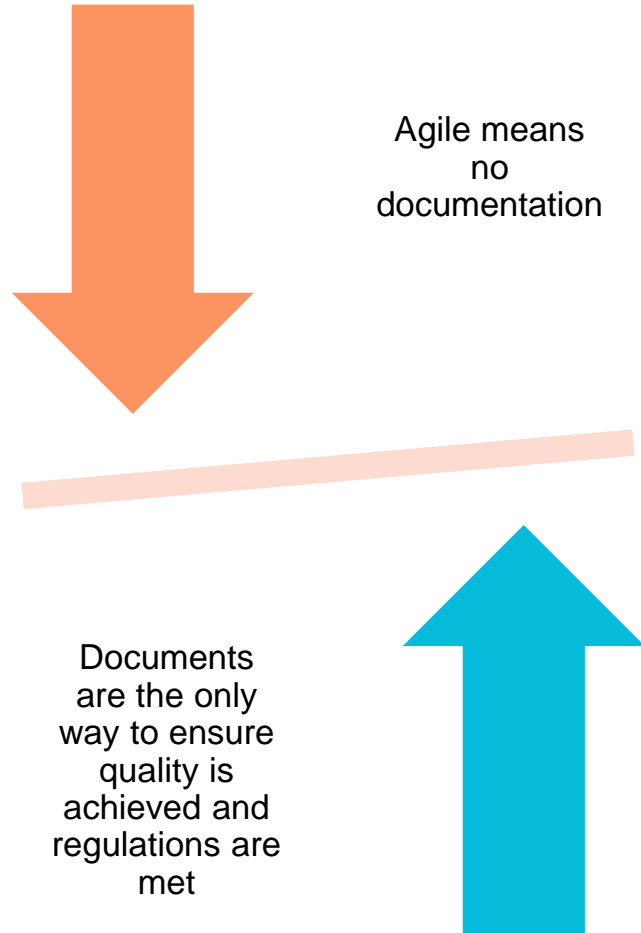
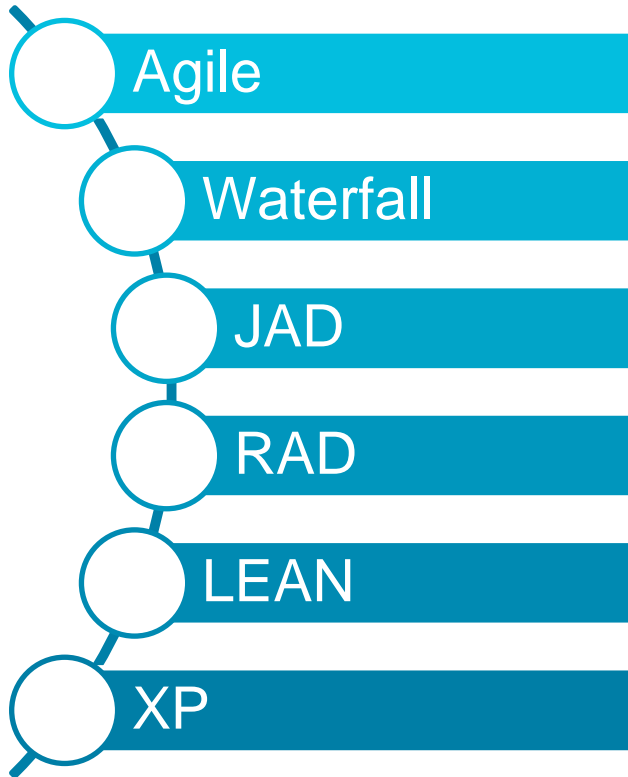
- What you say in your documentation is what you are doing

- Capture evidence of what you did



- 
1. Use global date format
 2. Never backdate
 3. Include page number in all docs
 4. Review doc properties
 5. Use single strike for incorrect entry
 6. Use proper signature
 7. Train before execute
 8. Rigorous test cycles
 9. Conduct informal testing to expedite

Methodology



Tips:

1. Document methodology and deliverables in a project plan
2. Understand the team culture
3. Use the right mix of methodologies
4. Develop integrated program plan
5. Leaders prefer high-level visuals (roadmap, GANTT chart, etc.)



Use Case - Technology

Health Care & Life Sciences (HCLS)



Technology



Technology | Regulatory Fines



Equifax

- **\$575M**
- Lost personal & financial data of ~150M people



Instagram

- **\$403M**
- Violated children's privacy under the GDPR



TikTok

- **\$370M**
- Violated children's data privacy under GDPR



Meta

- **\$277M**
- Compromised 500 million users' personal information



Google

- **\$102M**
- Inappropriate cookie consent on YouTube



Technology | Revenue Comparison

How long it takes to earn \$1B?

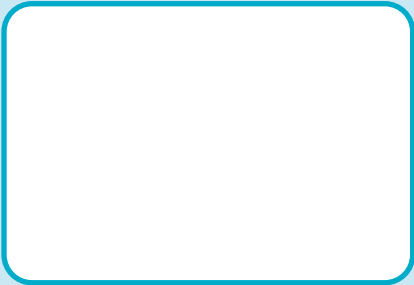


Source: FastCompany.com

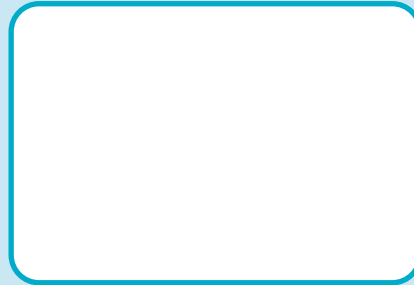
- The annual revenue of big tech companies dwarfs total fines.
- Big Tech companies can further water down the potential sting of these fines by delaying payments by filing appeals.

Regulations in Technology

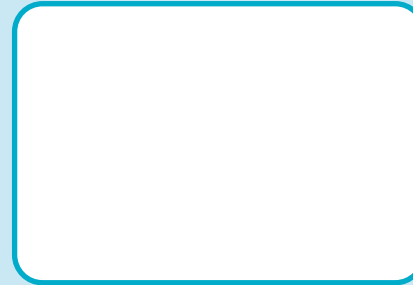
General Data Protection Regulation (GDPR)



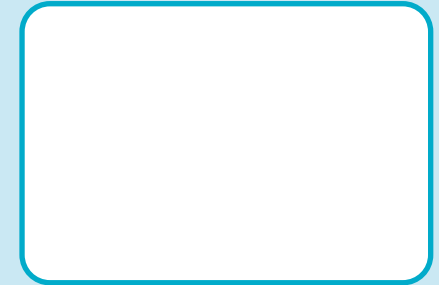
California Consumer Privacy Act (CCPA)



Digital Services Act (DSA)



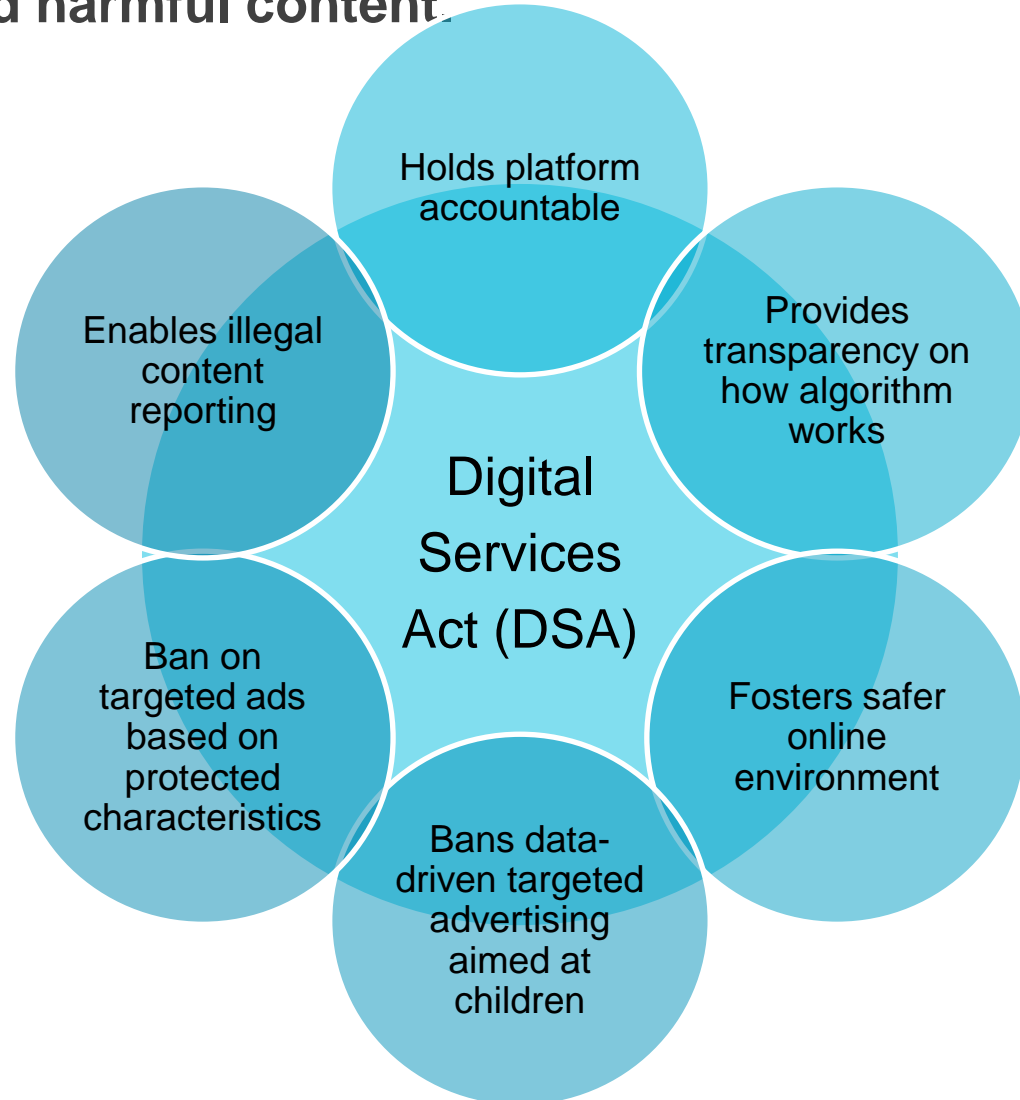
Digital Markets Act (DMA)



- Europe has been at the forefront of privacy regulation in the world.
- The EU represents a tenth of the world's population and about a sixth of its GDP.
- By 2024, 75% of the Global Population Will Have Its Personal Data Covered Under Privacy Regulations †

Digital Services Act (DSA)

DSA regulates online platforms (marketplaces, social media, app stores, etc.) by preventing illegal and harmful content.



- Failure to comply result in fines of up to 6% of a company's global turnover.
- That could mean billions in fines for a company as large as Meta (2023 revenue*: \$135 billion).

*Source: Facebook

Digital Services Act (DSA)

amazon.de/s?k=cell+phone&rh=n%3A562066%2Cp_89%3AGoogle&dc&language=en&ds=v1%3ADcAqHbnyNCnV2Y%2FJ8or8zZc...

amazon.de Electronics & Photo cell phone EN

All Customer Service Drugstore & Body Care Amazon Basics Today's Deals Buy Again Best Sellers Gift Ideas Home & Kitchen New Releases Gift Cards Shopper Toolkit Books

Electronics & Photo Promotions Best Sellers Smartphones & Phones TV & Video Audio Camera & Photo Navigation & Car HiFi Electronics Accessories Music- & DJ-Equipment Amazon Business

1-24 of 122 results for "cell phone"

Selected filters (2) Clear all

X Electronics & Photo X Google

Eligible for free delivery

Free Delivery by Amazon

Free Shipping by Amazon to eligible destinations

Department

< Any Category

Electronics & Photo

- Car & Vehicle Electronics
- Household Batteries, Chargers & Accessories
- Computers, Components & Accessories

Results

Learn about these results. Check each product page for other buying options.



Amazon Exclusive

Sponsored ⓘ

Google Pixel 7a and Charger - 5G Enabled Android Smartphone without SIM Lock with Wide Angle Lens and Impressive Battery Life - Sea

★★★★☆ ~ 252

200+ bought in past month

€399⁰⁰ RRP: €509.00

Delivers to United States

Add to Basket

+2 colours/patterns

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You're seeing this advertisement based on one or more of the following:

- The search terms you used or the content or products you are viewing on this page
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About the advertiser

- Advertiser name: Google Germany GmbH
- Who paid for this advertisement: Google Germany GmbH

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View and edit your advertisement settings.

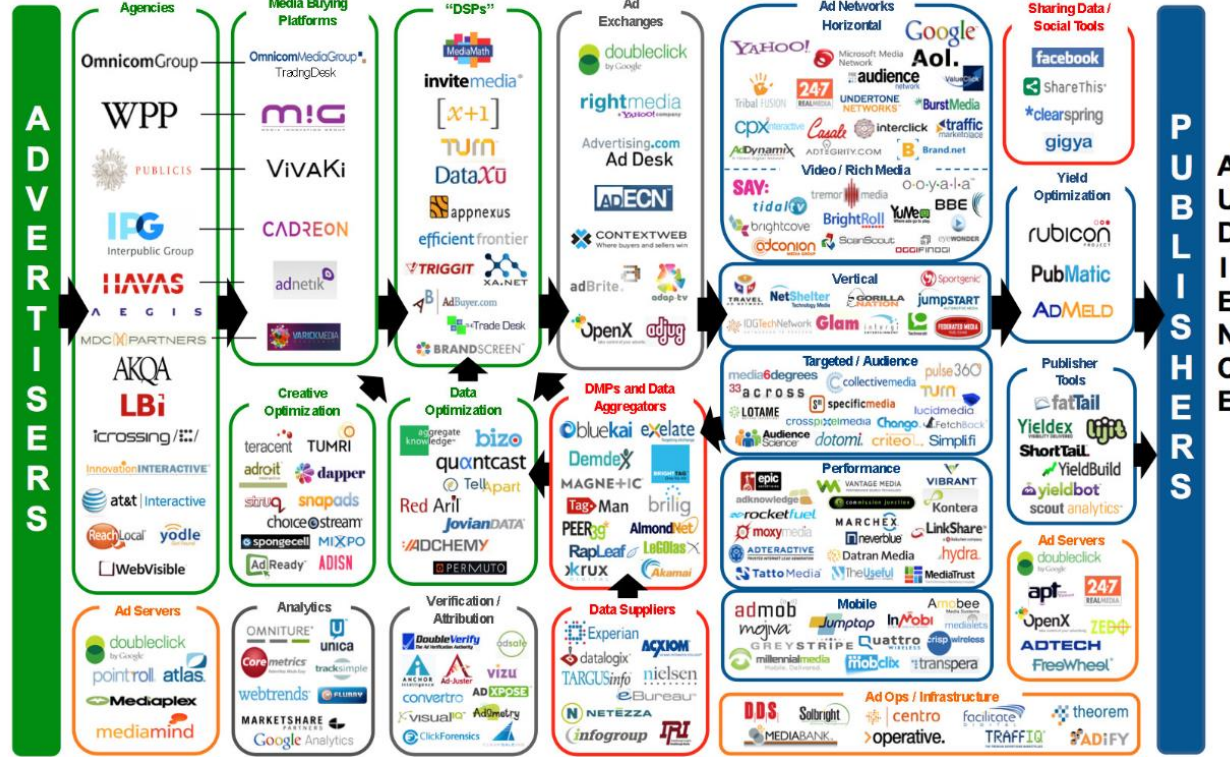
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Complex Architecture

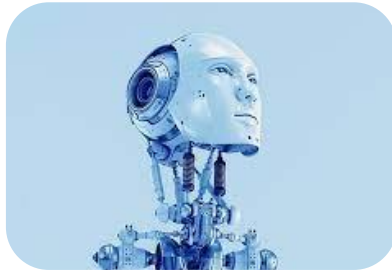


Display Advertising Technology Landscape



1. Understand the tech stack / architecture
2. Identify all the impacted teams (often hundreds of teams)
3. Seek leadership alignment on the priority of regulatory programs
4. Secure resource commitment
5. Review cross-regulatory impacts
6. Analyze financial impact
7. Seek sign-off on key deliverables
8. Continue to partner with legal and regulatory stakeholders
9. Conduct periodic leadership update meetings
10. Secure regional resources for testing local regulations

Emerging Technologies



Artificial
intelligence (AI)



Machine
learning



Big data
analytics



Internet of
Things (IoT)



Autonomous
Vehicles

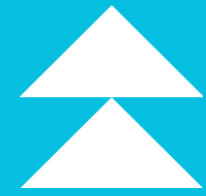


Drones

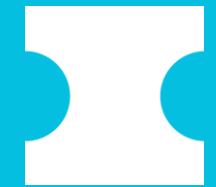
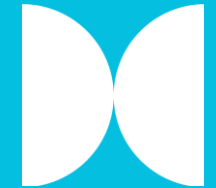
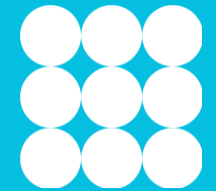
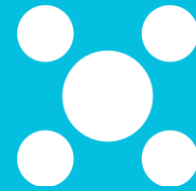
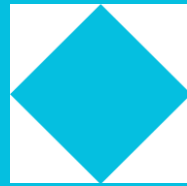


Block Chain

How to best protect citizens, ensure fair markets, and enforce regulations, while allowing these new technologies and businesses to flourish?



Challenges & Recommendations



Constraints



- **Non-Negotiable Compliance:** Compliance is not a choice but an essential requirement for operations.

Scope

- **Dynamic Regulatory Landscape:** Acknowledging that regulatory environments are dynamic.

Quality

- **Lawful Innovation:** Striving to innovate while respecting legal constraints is key to sustained growth and compliance.

Cost

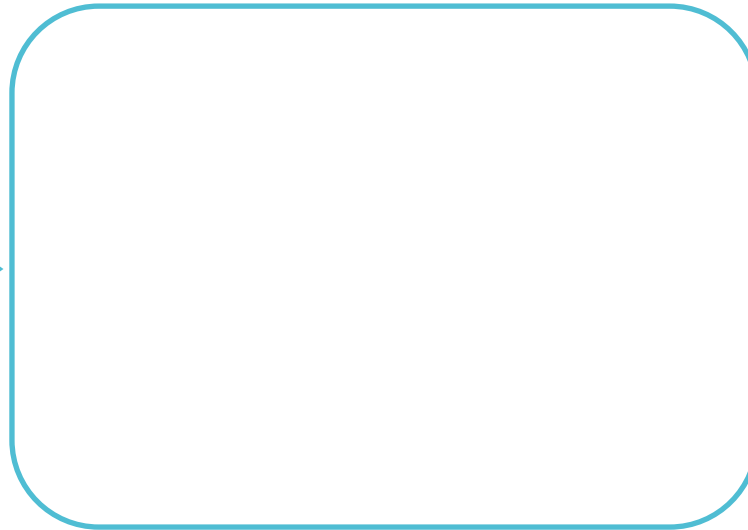
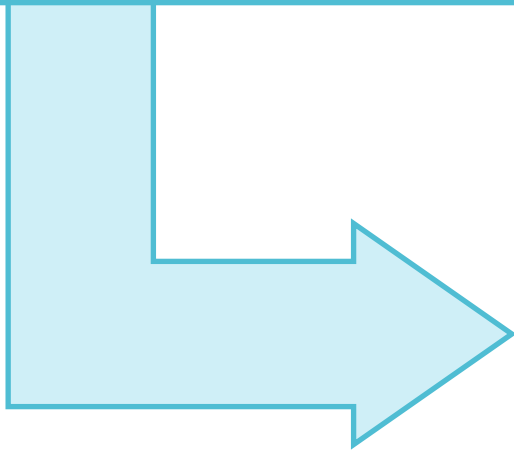
- **Market Impact:** Regulations impose constraints on the speed of development, affecting time-to-market strategies and influencing a company's ability to revolutionize its industry.

Time

Regulatory Requirements




- Evolving & ambiguous regulatory requirements
- Conflicting regulatory requirements



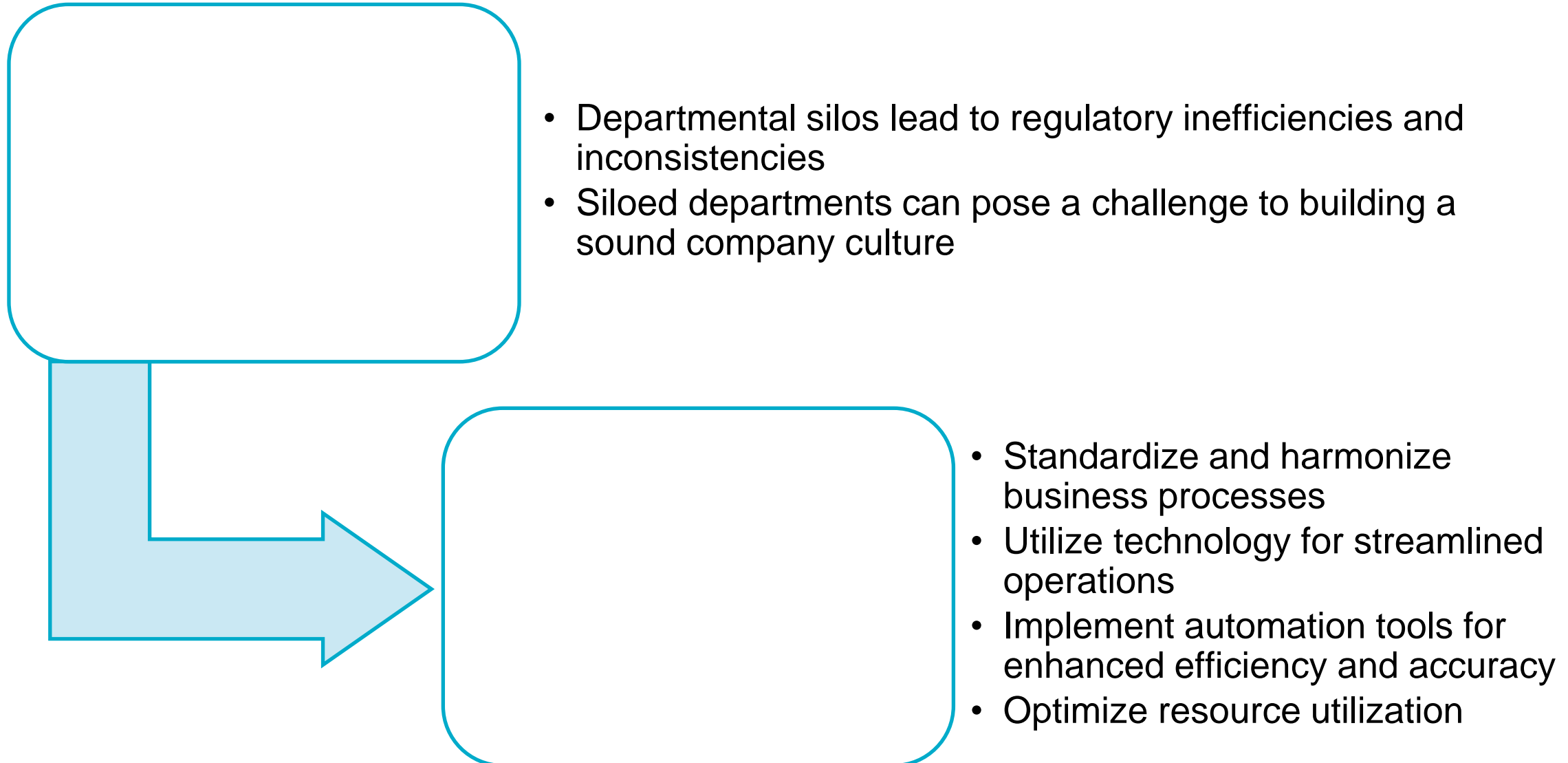
- Develop a comprehensive compliance framework
- Consult with industry/domain experts
- Engage proactively with regulators
- Provide input on proposed regulations

Business Requirements

- 
- Risk of disclosing business secrets
 - Delay due to ambiguous requirements

- Participate in industry discussions
- Seek guidance from legal
- Accelerate by developing various requirements docs, but maintain balance
- Conduct regular reviews
- Innovate in uncharted territory, where regulations may not be well-defined.

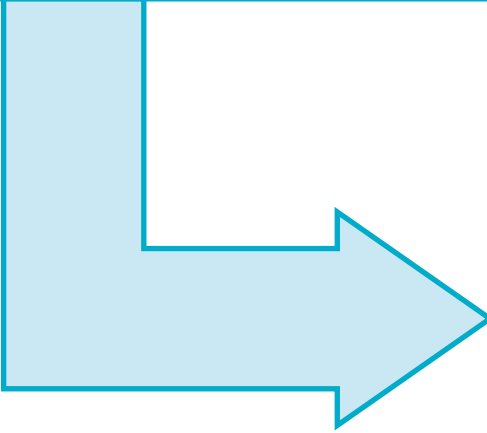
Organizational Barriers

- 
- Departmental silos lead to regulatory inefficiencies and inconsistencies
 - Siloed departments can pose a challenge to building a sound company culture

- Standardize and harmonize business processes
- Utilize technology for streamlined operations
- Implement automation tools for enhanced efficiency and accuracy
- Optimize resource utilization

Organizational Goals

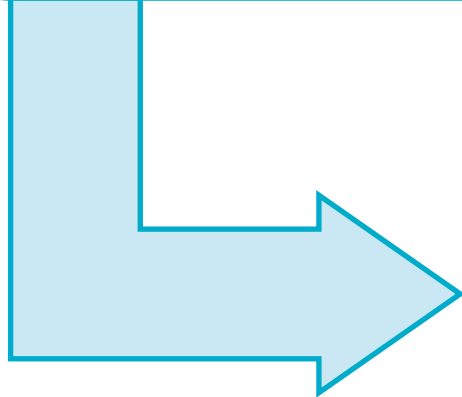
- Regulatory programs do not generate revenue
- Conflicting organization goals and priorities

- 
- Ensure leadership mandate
 - Treat regulatory programs on par with keeping the lights on
 - Obtain stakeholders buy-in
 - Educate and raise awareness

Resource Constraints



- Compliance demands substantial resources
- Smaller organizations may struggle to allocate resources

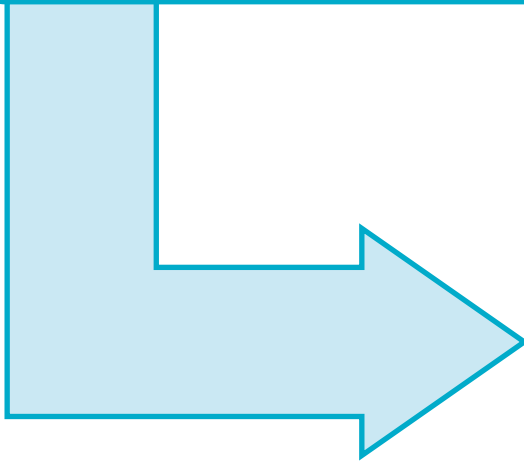


- Focus resources on areas with the highest compliance and business impact
- Optimize resource allocation by aligning skilled personnel with specific tasks
- Ring fence resources

Timeline



- Non-negotiable timeline

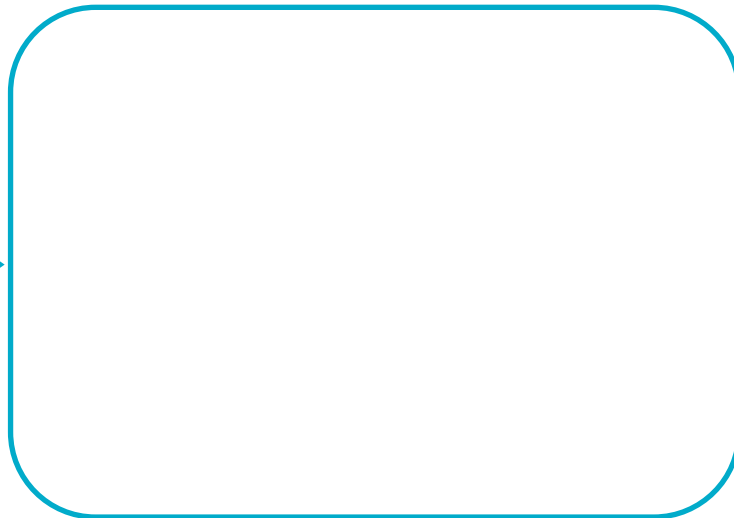
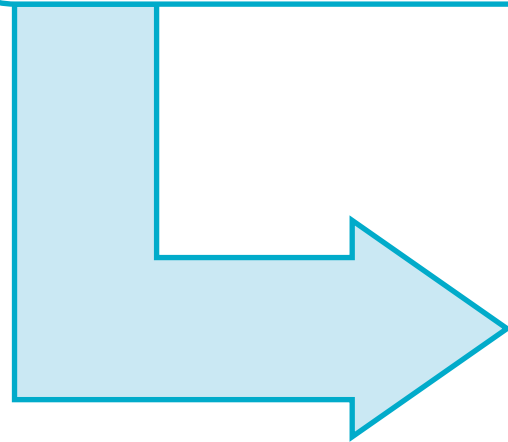


- Develop a working backwards plan
- Identify regulatory vs business requirements

Cross Functional Impact



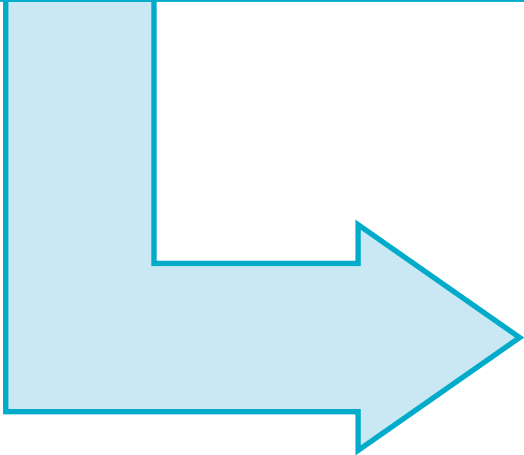
- Impact across several business units
- Complexity exponential increases with number of teams



- Identify all the impacted teams as early as possible
- Gain support from impacted teams
- Define roles and responsibilities
- Use a hub-spoke model of distributed responsibilities, if that works.

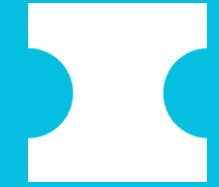
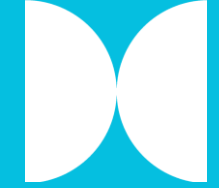
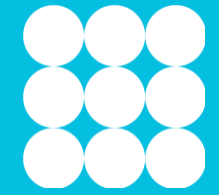
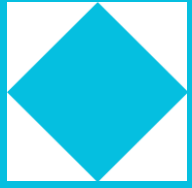
Ongoing Compliance

- Maintaining readiness for audits
- Ongoing updates in regulations require constant monitoring
- Retaining resources post compliance program

- 
- Staying informed about the regulatory landscape
 - Conduct comprehensive training
 - Identifying and mitigating new risks



Resources: Tools and Templates

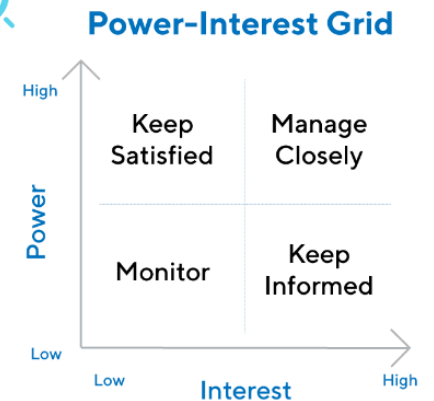


Stakeholder Register

Stakeholder Register may contain politically sensitive information. Ensure this document is appropriately secured.

TEAM	NAME	TITLE	ROLE	SUPPORT LEVEL	POWER LEVEL	INTEREST LEVEL	COMMUNICATION	OTHER CHARACTERISTICS	POWER-INTEREST
Supply Chain	Stakeholder 1	VP	Sponsor	Supports	High	High	Email Monthly	Prefers phone or email	Manage Closely
Finance	Stakeholder 2	VP	Fin Lead	Neutral	High	Medium	Email Monthly	Likes sports	Manage Closely
QA	Stakeholder 3	Sr. Mgr.	Quality Mgr.	Opposes	Medium	Medium	Weekly touchpoint	Does not like text messages	Keep Satisfied
Engineering	Stakeholder 4	Sr. Mgr.	Eng. Mgr.	Supports	Medium	High	Weekly touchpoint	Process oriented	Keep Satisfied
R&D	Stakeholder 5	Scientist	ML Scientist	Supports	Low	Medium	Weekly touchpoint	Passionate about the product	Keep Informed
HR	Stakeholder 6	Mgr.	HR Lead	Neutral	Low	Medium	Quarterly Report	Likes to be kept in the loop	Keep Informed
Sales	Stakeholder 7	Mgr.	Sales Lead	Opposes	Low	Low	Quarterly Report	Likes to be kept in the loop	Monitor

1. Start by brainstorming to identify all the stakeholders.
2. Understand the expectations and concerns by conducting interviews, surveys, workshops, or 1-1 meetings.
3. Determine the level of influence and power each stakeholder.
4. Assign priorities and engagement strategies.
5. Regularly review and update as stakeholder matrix is a dynamic document.



Detailed Project Plan

#	Task	Start Date	End Date	Duration	Dependency	Resource



- 1. Ensure all the project tasks roll-up to a line in the project plan.**
- 2. Ensure start date and end date/duration for each task.**
- 3. Set dependencies (SS, FF, SF, FS) along with lead/lag.**
- 4. Ensure committed named resources along with the allocation [25%, 50%, 100%].**

Financial Management



Category	Description	Estimate to Complete (ETC)	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
			Actuals	Actuals	Forecast	Forecast	Forecast	Forecast	Forecast	Forecast	Forecast	Forecast	Forecast	Forecast
CAPEX														
Hardware														
Hardware 1														
Hardware 2														
Software														
Software 1														
Software 2														
Internal H/C														
Resource A	Designer													
Resource B	Developer													
Consulting														
Vendor A														
Vendor B														
Travel														
Design workshop														
Design Review														
Contingency														
TOTAL CAPEX														
OPEX														
Software														
Software 1														
Software 2														
Internal H/C														
Resource X	Program Manager													
Resource Y	Project Manager 1													
Resource Y	Project Manager 2													
Travel														
Planning														
Launch Party														
Communications / Training														
Contingency														
TOTAL OPEX														
Total Project Costs														

1. Partner with finance to understand the financial process.
2. Clarify the Opex/Capex classification (e.g.: Headcount, Software, Travel, etc.)
3. Ensure project budget is in line with the project plan.
4. Obtain quote from vendors to ensure accurate budgeting. Confirm the amount in the SOW.
5. Account for supply chain delays for any procurement.
6. Confirm policies around project delays (use-it or lose-it).

Resource Management

TEAM	NAME	ROLE	Aug	Sep	Oct	Nov	Dec	TOTAL
Team Alpha	John	Lead	25%	25%	25%	25%	25%	125%
Team Alpha	Jane	Architect	100%	100%	0%	0%	0%	200%
Team Alpha	Mary	Developer	100%	100%	100%	0%	0%	300%
Team Alpha	Amy	Scientist	25%	25%	25%	25%	25%	125%
Team Beta	Peter	UX Designer	25%	25%	0%	0%	0%	80%
Team Beta	Sara	Writer	25%	25%	0%	0%	0%	50%
Total FTE			3	3	2.5	0.5	0.5	



- **Ensure project task assignment is in line with the resource allocation.**
- **Coordinate with functional managers and ensure resource is not overallocated.**

RAID (Risks, Actions, Issues, Decisions) Tracker

Risk Tracker

NAME	MITIGATION	STATUS	OWNER	SEVERITY	PROBABILITY	RISK FACTOR	TRIGGER DATE	LOGGED DATE
Delay in onboarding resource will impact launch		In Progress	Girish	High	High	High	29-Feb-2024	15-Jan-2024

Action Tracker

DESCRIPTION	OWNER	STATUS	PRIORITY	LOGGED DATE	DUE DATE	LOGGED BY
	Girish	In Progress	Medium	15-Feb-2024	29-Feb-2024	John

Issue Tracker

#	TITLE	DESCRIPTION	OWNER	LOGGED DATE	TRIGGER DATE	IMPACT	RESOLUTION

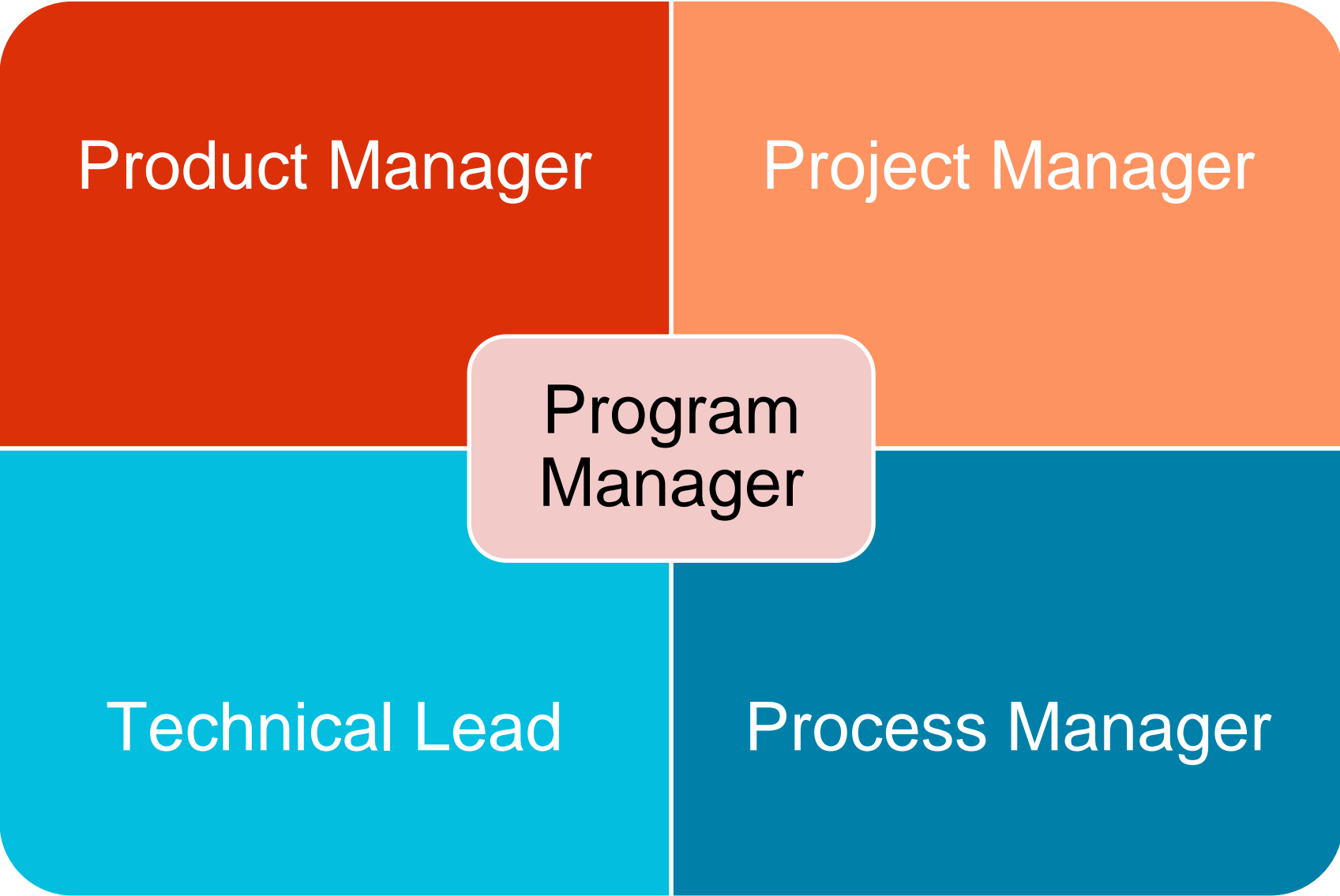
Decision Tracker

#	TITLE	DESCRIPTION	DECISION MAKER	IMPACT	DECISION DATE



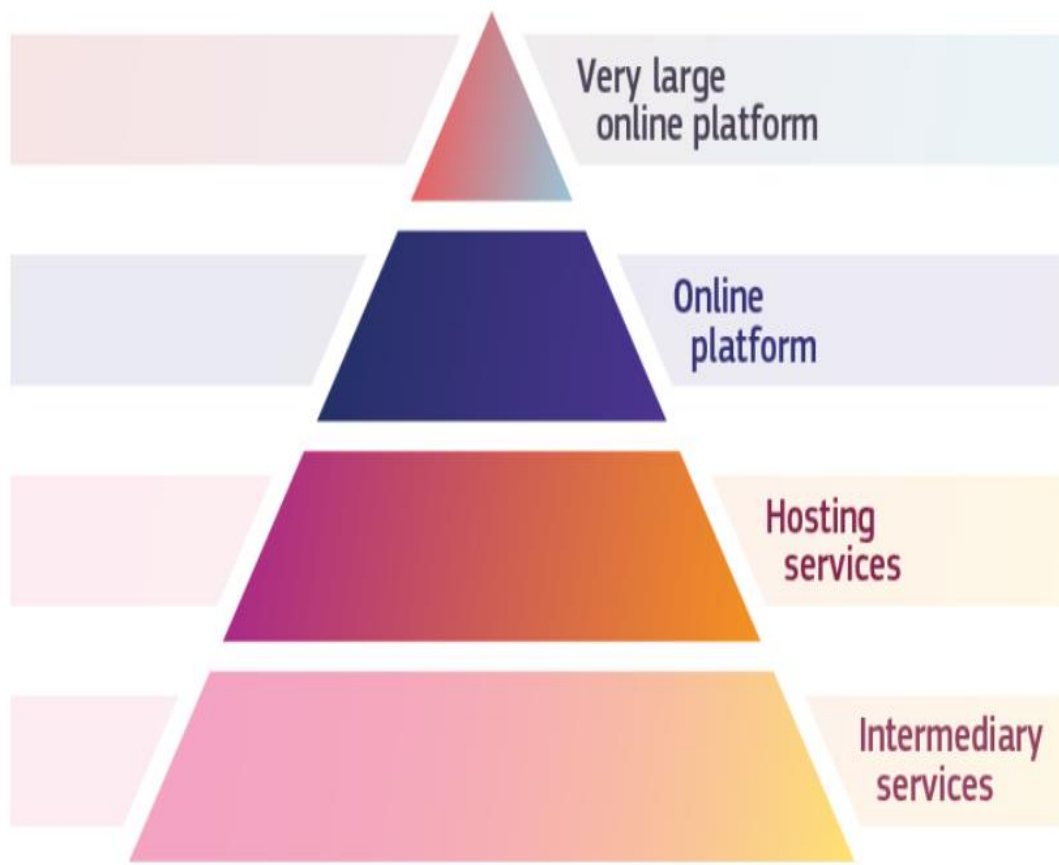
- State risk with mitigation
- Include trigger date by when the risk
- Identify owner for each risk.
- Determine risk factor, which is a combination of probability and business impact.
- Use Action tracker for program level action items.
- If a risk is not mitigated by the trigger date, it becomes an issue.
- Issues are not mitigated. Instead they are resolved with an action plan.
- Publish key program level decisions along with the name of the decision maker.

Skillset



Digital Services Act (DSA)

The **Digital Services Act (DSA)** regulates online platforms (marketplaces, social networks, content-sharing platforms, app stores, and online travel and accommodation platforms) by preventing illegal and harmful activities online. It ensures user safety, protects fundamental rights, and creates a fair and open online platform environment.



Very large online platforms and search engines pose particular risks in the dissemination of illegal content and societal harms. Specific rules are foreseen for platforms reaching more than 10% of 450 million consumers in Europe.

Online platforms bring together sellers and consumers such as online marketplaces, app stores, collaborative economy platforms and social media platforms.

Hosting services such as cloud and web hosting services (also including online platforms).

Intermediary services offering network infrastructure: Internet access providers and domain name registrars (also including hosting services).

DSA Online Platforms

The EU considers very large online platforms (or very large online search engines) as those with over 45 million monthly users in the EU. So far, the EU has designed 19 platforms and search engines that fall into that category, including the following:

- Alibaba AliExpress
- Amazon Store
- Apple App Store
- Booking.com
- Facebook
- Google Play
- Google Maps
- Google Shopping
- Instagram
- LinkedIn
- Pinterest
- Snapchat
- TikTok
- Twitter
- Wikipedia
- YouTube
- Zalando
- Bing
- Google Search

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