

Aligning, Streamlining, Integrating: Strengthening CMC Partnerships in pharma operations

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Agenda

01. Streamlining Data Sharing

Accelerate approvals and enhance product lifecycle management through unified platforms.

02. Bridging Quality Operations

Connect quality and operations for efficient regulatory compliance and seamless workflows.

03. Building Robust Partnerships

Navigate complex CMC requirements with agility through strategic collaborations.

04. Advanced Analytics Integration

Real-time monitoring and proactive quality management for operational excellence.

05. Slide By Slide Source Of Information

Strategic CMC Partnership Framework

Mission & Vision

Transform pharmaceutical operations through integrated collaboration, ensuring regulatory compliance while accelerating innovation and market access through strategic partnerships and unified systems.



Innovation Acceleration

Align manufacturing and regulatory teams for seamless CMC integration and streamlined data sharing to accelerate approvals.



Operational Excellence

Foster collaboration between quality and operations for efficient compliance and build robust partnerships for agility.



Data Fragmentation Challenge Analysis

Current State Challenges

Fragmented data across regulatory, quality, and manufacturing functions creates significant delays and inefficiencies.



Impact on Timelines

Siloed systems hinder collaboration, manual processes delay resolution, and lack visibility creates risks.

Market Access Impact

Fragmentation challenges directly impact time-to-market requiring immediate strategic intervention and solutions.



Integration Gaps

Misalignment on priorities, inconsistent documentation, and audit readiness issues across functions.

Digital Platform Implementation Roadmap

Centralized Repository

Implement Veeva Vault as unified repository for regulatory and quality data access.

Standardization

Adopt IDMP and SCA standards for consistent data formats and compliance.

Collaborative Integration

Deploy Accumulus Synergy for streamlined regulatory engagement and transparency.

Seamless Ecosystem

Create integrated tools enabling data flow for faster approvals.



Key Digital Platform Technologies

Essential platforms driving CMC transformation through integrated data management, standardized processes, and enhanced regulatory collaboration across global pharmaceutical operations.

Platform	Primary Function	Key Benefits	Implementation Impact
Veeva Vault	Cloud regulatory information management	Secure collaboration, scalability	Unified data access
ISO IDMP	Standardizes medicinal product data	Global compliance, data integrity	Regulatory harmonization
FHIR	Healthcare data interoperability	Efficient data exchange	Improved workflows
Accumulus Synergy	Real-time regulatory collaboration	Simultaneous submissions	Regulatory agility

Impact Metrics: Approval & Lifecycle Enhancement

30-35%

Faster Approvals

Accelerated Approvals

- Streamlined data sharing reduces dossier preparation time significantly.
- Reduced preparation time through unified systems
- Faster regulatory processes and market entry
- Enhanced manufacturing-regulatory collaboration

40%

Lifecycle Efficiency

Proactive Lifecycle Management

- Early data signals enable proactive decisions reducing changes by 40%.
- Early detection of trends for proactive decisions
- 40% reduction in post-approval change time
- Enhanced lifecycle through predictive analytics

Bridging Quality and Operations: Digital Framework

Agile Quality Management

QualiPSO program enhances data integrity and operational efficiency through standardized electronic records.

Cross-Functional Teams

Enhanced collaboration improves decision-making and resource allocation across global operations.



Digital Tools Integration

Veeva QMS and QualityDocs streamline change control with automated workflows and real-time visibility.

Market Expansion Support

Standardized processes enable efficient expansion and early integration reduces development risks.

GMP and Regulatory Functions Integration

Alignment Challenge

Inspection findings reveal gaps between filed commitments and actual operational practices requiring intervention.

Linked Change Control

GMP changes directly connect with regulatory variation filings for seamless integration.

**Systematic
Integration**

Market Access Delays

Inconsistencies between GMP records and regulatory submissions create delays in market access.

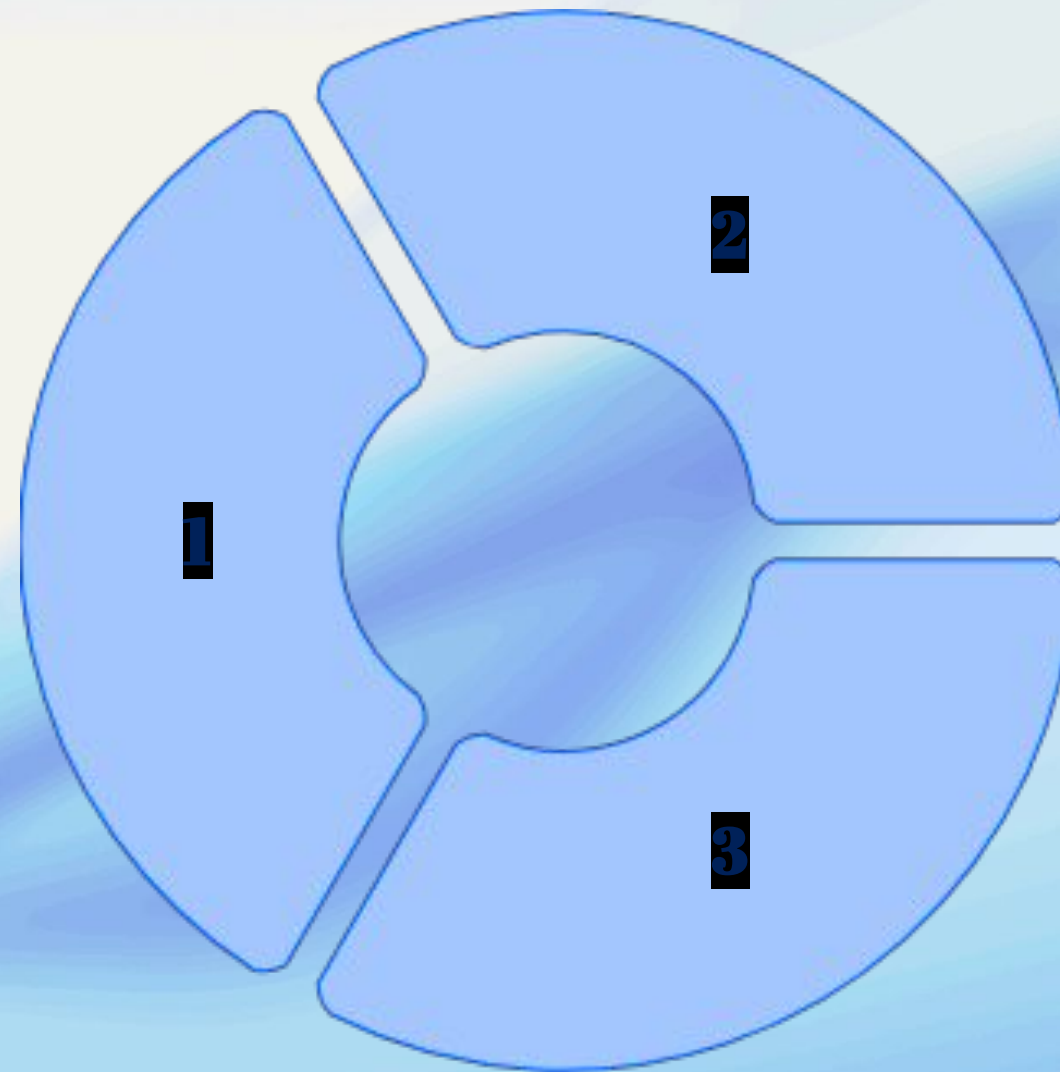
Data Synchronization

QMS and regulatory submissions use consistent data ensuring accuracy and compliance.

Building Robust CMC Partnerships

Early Collaboration

Manufacturing and regulatory teams collaborate from development to commercialization for seamless integration.



Digital Benefits

Strong internal and external partnerships enhance resilience in dynamic regulatory environments.

Agility Focus

Navigate complex CMC requirements with strategic digital transformation initiatives.

Innovation, Compliance & Scalability Balance

1

Innovation Drivers

New product development and differentiation through cutting-edge technologies and collaborative research initiatives.

2

Compliance Requirements

Safety standards and regulatory adherence through rigorous quality systems and comprehensive documentation.

3

Scalability Enablers

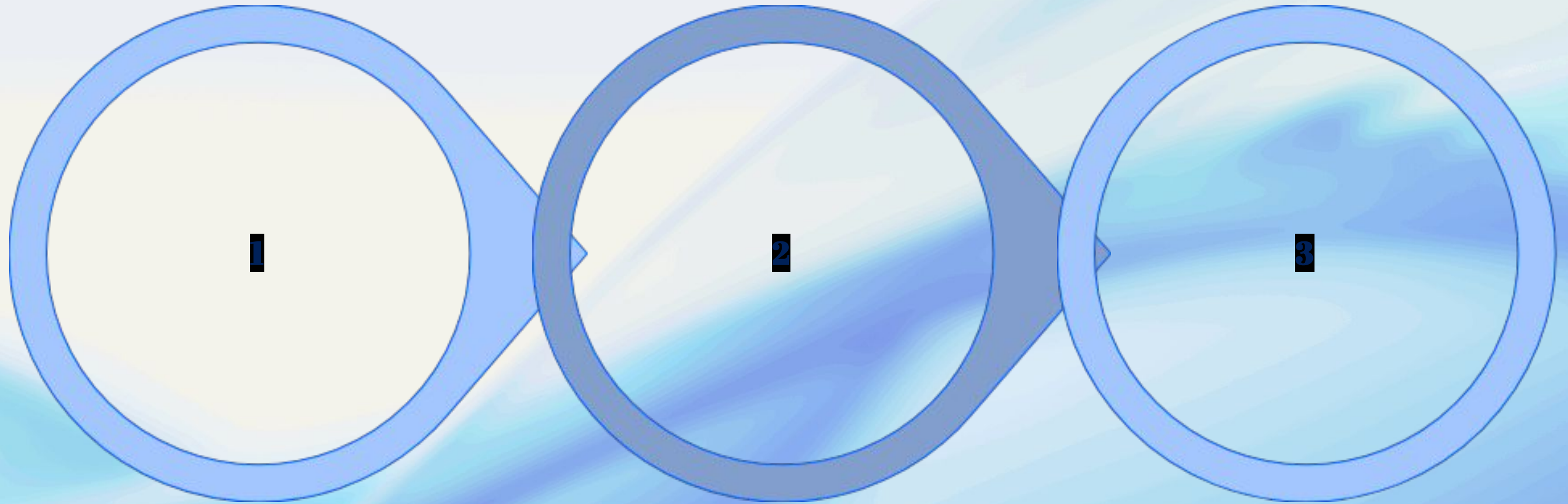
Efficient expansion capabilities and consistent operations across multiple geographic locations.

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Strategic Balance

Collaborative alignment prevents delays and ensures sustainable competitive advantage in global markets.

Manufacturing-Regulatory Team Alignment Process



Early Collaboration

Teams collaborate from development understanding constraints and expectations for seamless integration.

Joint Planning

Shared risk assessments and integrated strategies improve compliance and streamline submissions.

Accelerated Outcomes

Cross-functional alignment enables faster launches with built-in compliance reducing delays.

Advanced Analytics for Real-Time CMC Monitoring

Real-Time Analytics Integration

Advanced analytics enable continuous tracking of critical quality attributes with immediate visibility into performance metrics.



Real-Time Monitoring

Continuous tracking provides immediate visibility into performance metrics.



Predictive Quality

AI insights transform quality management from reactive to proactive approaches.



Enhanced Decision-Making

Accelerates decision-making speed and improves regulatory compliance confidence.

Fostering Collaborative Culture



Building Trust

- Open communication channels across departments
- Continuous learning and knowledge sharing
- Shared mission alignment toward goals



Leadership Collaboration

- Regular cross-functional dialogue sessions
- Reward systems for collaborative behaviors
- Joint problem-solving workshops

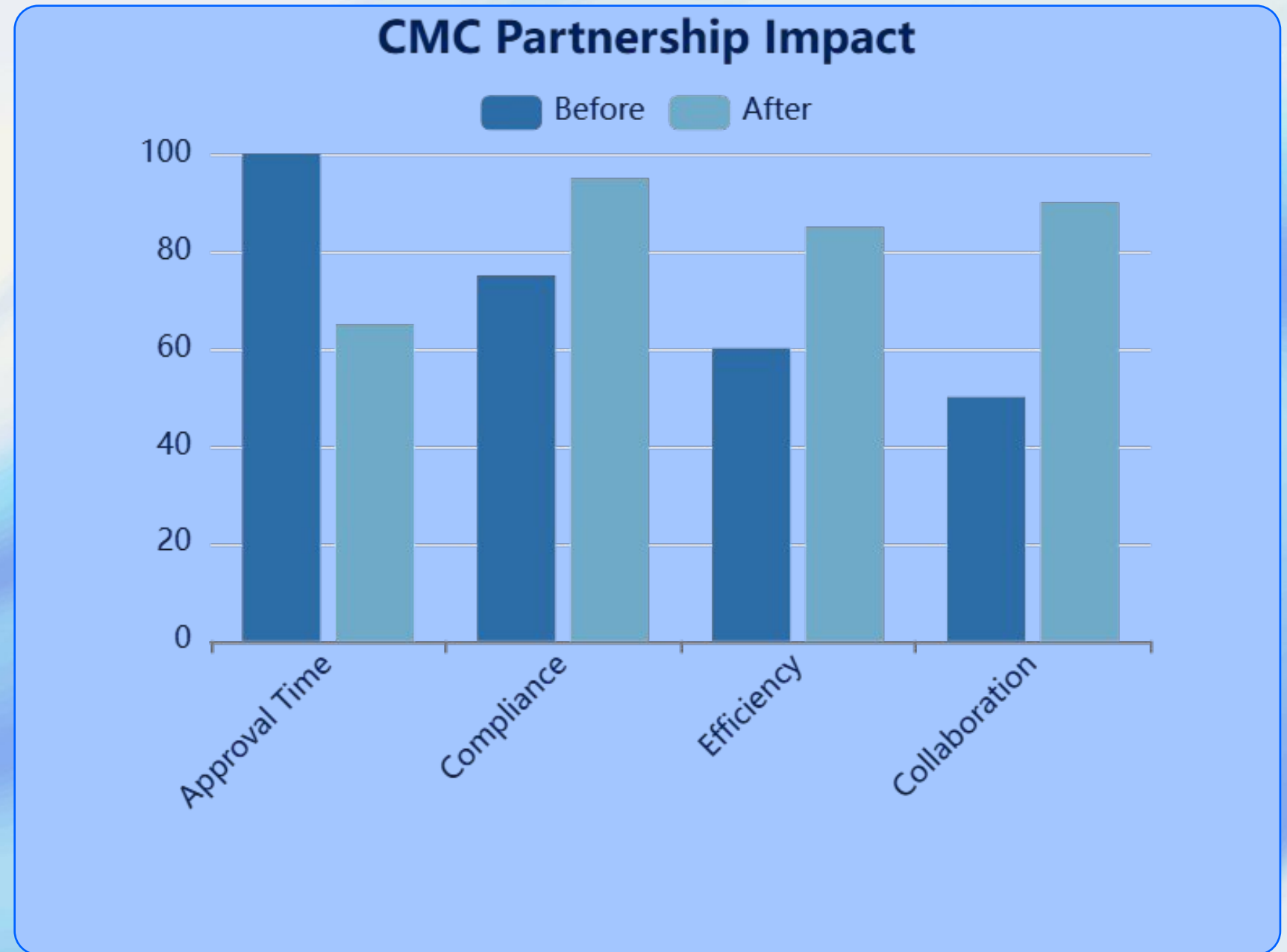
Real-World Impact: Integrated CMC Success

Implementation Results

Organizations implementing integrated CMC partnerships demonstrate measurable improvements in approval timelines, regulatory compliance, and operational efficiency through strategic collaboration and digital transformation initiatives.

35%

Faster Approval Timelines



Key Performance Indicators & Outcomes

Success Metric	Baseline	Target	Achieved	Impact
Dossier Preparation	100 days	70 days	65 days	Enhanced efficiency
Approval Timeline	18 months	12 months	13 months	Faster market access
Cross-functional Alignment	60%	85%	90%	Improved collaboration
Data Integration Level	45%	80%	85%	Better decision-making
Regulatory Compliance	88%	95%	96%	Reduced risk

94%

Stakeholder Satisfaction

96%

Overall Compliance Achievement

Case Study: Digital Transformation Excellence



Culture of Trust

- Sanofi fosters collaboration through trust and transparency across teams.
- Enables seamless integration of regulatory and manufacturing functions.
- Shared mission drives operational excellence and compliance.



Hybrid Work Digital Tools

- Hybrid models with digital tools support cross-functional engagement.
- Real-time collaboration across global teams enhances efficiency.
- Streamlined decision-making through integrated technology platforms.



Innovation Scalability

- Collaborative approaches enable continuous innovation and scalable operations.
- Organizations adapt swiftly to market changes and requirements.
- Integrated teamwork supports sustainable competitive advantage.

Success Stories: Digital Transformation Cases

Digital Excellence

Leading companies achieve success through integrated CMC partnerships with measurable regulatory and operational improvements.

Accumulus Synergy

- Real-time regulatory connectivity platform
- 90% reduction in approval timelines
- Rapid global submissions capability

Project Orbis

- FDA concurrent drug review framework
- Streamlined global communication
- Accelerated patient access worldwide

Sanofi Excellence

Digital transformation
optimizing regulatory workflows.

Measurable Impact

Automated flows improve
efficiency and alignment.

Industry Leadership

Setting CMC partnership success
benchmarks.

Slide-by-Slide References

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Slide 3: Strategic CMC Partnership Framework - Industry Best Practices Analysis

Slide 4: Pharmaceutical Operations Analysis - Data Integration Challenges Study

Slide 5: Veeva Vault Documentation; IDMP Standards; Accumulus Synergy Platform Specifications

Slide 6: Digital Platform Technology Assessment - Regulatory Technology Solutions Analysis

Slide 7: Industry Benchmarking Studies - CMC Performance Metrics

Slide 8: QualiPSO Program Documentation; Veeva QMS Implementation Guidelines

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Slide 10: Enhanced CMC Presentation - Partnership Impact Analysis

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Slide 13: Advanced Analytics Implementation - Real-Time CMC Monitoring Solutions

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Slide 15: Sanofi LinkedIn Post - Transforming Regulatory Affairs, November 2024

Slide 16: Real-World Implementation Studies - Integrated CMC Success Metrics

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Thank you for your engagement. Together, we can transform pharmaceutical operations through strategic CMC partnerships.