



**SUPPLY CHAIN
WIZARD**

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Planning and Executing NDC12

A Cross-Functional Program Framework for Pharma Companies

From regulatory readiness to coordinated enterprise execution.

SUPPLY CHAIN WIZARD

Pharma Supply Chain Specialists | Global Leader

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NDC12 is not one project. It is a program.

This white paper provides a practical operating model for aligning functions, systems, data and external partners around one execution roadmap.

Executive Summary

NDC12 is no longer just a regulatory topic for pharmaceutical companies to monitor. With the new 12-digit National Drug Code format now defined and an effective date established, the focus is shifting from awareness to execution.

The challenge is that NDC12 does not belong neatly to one department.

Regulatory Affairs may interpret the requirement. Information Technology may update systems. Packaging and Labeling may change artwork and barcodes. Supply Chain may manage inventory and product flows. Finance may need to assess billing, rebates, chargebacks, reimbursement, and reporting dependencies. Commercial teams may need to coordinate product data with customers and channel partners.

External organizations add another layer of complexity. Wholesalers, distributors, third-party logistics providers, technology vendors, contract manufacturers, data providers, payers, and other trading partners may each have their own transition plans and timelines.

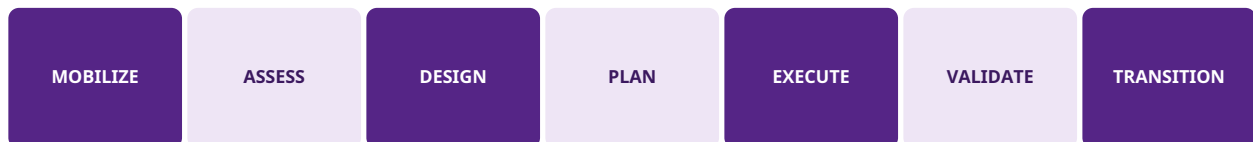
The result is not a traditional compliance project.

NDC12 is a cross-functional transformation program that requires coordinated planning, clear ownership, structured governance, dependency management, testing, and controlled execution.

Without this structure, organizations risk creating disconnected workstreams where departments solve their own portion of the transition independently. That can lead to inconsistent data rules, duplicated effort, missed dependencies, late system changes, partner misalignment, and operational disruption.

This white paper introduces a practical framework for planning and executing NDC12 as an enterprise program.

The recommended approach follows seven stages:



The objective is to give pharmaceutical companies a repeatable way to move from regulatory understanding to enterprise readiness while maintaining control across functions, systems, products, and external partners.

1. Why NDC12 Requires a Program, Not a Project

A traditional project normally has a defined owner, a relatively contained scope, and a clear set of deliverables.

NDC12 is different.

The National Drug Code is embedded across the pharmaceutical operating model. It can appear in product master data, regulatory records, labels, enterprise systems, financial transactions, warehouse processes, reporting, customer data, external integrations, and downstream healthcare workflows.

That means one change creates multiple dependencies.

An Information Technology team may successfully update an enterprise resource planning system to accept 12-digit values.

But that does not automatically answer:

- How existing product records will be mapped
- How historical identifiers will be retained
- How labeling will be coordinated
- How external partners will exchange product data
- How financial processes will treat different NDC representations
- How legacy inventory will be handled
- How transition timing will be sequenced
- Which department owns exceptions
- How end-to-end readiness will be validated

These are enterprise decisions.

They cannot be resolved independently by one department.

For this reason, pharmaceutical companies should treat NDC12 as a **structured program containing multiple coordinated projects and workstreams**.

2. The Core NDC12 Execution Challenge

The biggest implementation risk is not necessarily the complexity of any individual system change.

It is the number of changes that must happen together.

A typical pharmaceutical organization may need to coordinate:

Regulatory requirements

What must change, when, and under which rules?

Product master data

How will NDC10, NDC11, NDC12, GTIN, and internal identifiers be governed?

Systems

Which applications store, transform, validate, or transmit NDC data?

Labeling and packaging

Which product labels, artwork, barcodes, and packaging configurations must change?

Supply chain operations

How will inventory, warehousing, distribution, returns, and trading-partner flows operate?

Commercial and Finance

Which customer, pricing, billing, chargeback, rebate, reporting, and contracting processes depend on product identity?

External partners

When will wholesalers, vendors, customers, and service providers become ready?

Quality and validation

How will the organization demonstrate that updated processes work correctly?

Individually, each issue is manageable.

Together, they create a complex dependency network.

That is why planning must begin with the enterprise operating model rather than a list of technical tasks.

3. The Departments That Need to Be Involved

NDC12 programs should be cross-functional from the beginning.

Regulatory Affairs

Regulatory Affairs should interpret requirements, monitor guidance, coordinate regulatory data implications, and ensure that implementation remains aligned with FDA expectations.

Regulatory Affairs should not, however, be expected to own every operational consequence of the change.

Information Technology

Information Technology will typically lead a significant portion of system remediation.

This may include:

- enterprise resource planning systems,
- master data systems,
- warehouse management systems,
- serialization platforms,
- labeling applications,
- middleware,
- reporting environments,
- integrations,
- external interfaces.

Technology teams need clear business rules before remediation begins.

Master Data and Data Governance

NDC12 creates a major product-data governance requirement.

This team should help define:

- authoritative data sources,
- identifier mappings,
- transformation rules,
- historical-data treatment,
- effective dates,
- stewardship responsibilities.

A central data model prevents individual systems from developing conflicting conversion logic.

Packaging and Labeling

Packaging teams must coordinate artwork, labeling, barcode configuration, inventory use-up, packaging schedules, and manufacturing timelines.

Changes must be synchronized with regulatory data and system readiness.

Supply Chain and Distribution

Supply Chain should assess:

- product identification,
- inventory,
- receiving,
- warehousing,
- picking,
- shipping,
- distribution,
- order management,
- returns,
- traceability,
- third-party logistics providers.

The physical transition of products must align with the digital transition of identifiers.

Finance

Finance should identify dependencies across:

- billing,
- pricing,
- chargebacks,
- rebates,
- reimbursement,
- contracting,
- revenue operations,
- financial reporting,
- government pricing.

Financial impacts are often discovered late if Finance is not included early.

Commercial and Market Access

Commercial teams need visibility into how NDC12 may affect:

- customer data,
- product launches,
- account management,
- contracting,
- channel partners,
- market access,
- commercial reporting,
- customer communication.

A technically correct transition can still create customer disruption if commercial dependencies are overlooked.

Quality

Quality teams should identify applicable validation and documentation requirements and determine how changes affect controlled processes and standard operating procedures.

Project Management Office

Because of the number of dependencies involved, a dedicated program management function is highly valuable.

The Project Management Office or program lead should coordinate:

- milestones,
- responsibilities,
- risks,
- issues,
- dependencies,
- resources,
- decisions,
- executive reporting.

This role becomes the connective layer across otherwise separate workstreams.

4. External Partners Must Be Part of the Plan

NDC12 readiness is not completely within the manufacturer's control.

A pharmaceutical company may depend on:

- wholesalers,
- distributors,
- third-party logistics providers,
- contract manufacturing organizations,
- contract packaging organizations,
- serialization providers,
- enterprise software vendors,
- master data providers,
- pharmacy benefit managers,
- payers,
- customers,
- government platforms.

Each may follow a different implementation timeline.

That creates a major planning question:

What happens when one organization is ready and the other is not?

Partner coordination therefore needs to begin well before cutover.

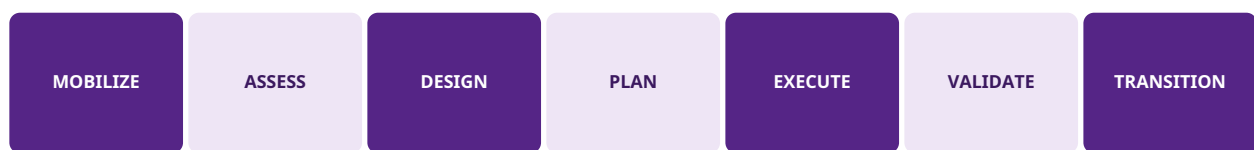
For every critical partner, organizations should understand:

- Current NDC usage
- Future-state expectations

- Planned system changes
- Target readiness date
- Testing availability
- Data exchange requirements
- Exception processes
- Contact and escalation ownership

A partner-readiness tracker should be managed as part of the central NDC12 program.

5. The Seven-Stage NDC12 Planning and Execution Framework



Stage 1: Mobilize

The first step is establishing ownership.

Organizations should define:

- Executive sponsor
- Program owner
- Program Management Office support
- Functional workstream leads
- Steering committee
- Decision-making authority
- Reporting cadence

This stage should also establish the program charter.

The charter should define:

Purpose

Why the organization is launching the NDC12 program.

Scope

Which business functions, products, markets, systems, and partners are included.

Governance

Who owns decisions and escalation.

Success criteria

What NDC12 readiness means for the organization.

KEY OUTPUT

NDC12 Program Charter and Governance Model

6. Stage 2: Assess

Before creating a detailed implementation plan, organizations must understand the current state.

The assessment should examine four areas.

Systems

Identify where NDC information is:

- stored,
- created,
- validated,
- converted,
- transmitted,
- reported.

Processes

Identify business processes that depend on product identifiers.

Examples include:

- product setup,
- regulatory listing,
- label generation,
- receiving,
- shipping,
- invoicing,
- chargebacks,
- rebates,
- reporting,
- returns.

Data

Document relationships among:

- NDC10,
- NDC11,
- NDC12,
- GTIN,
- internal product codes,
- packaging hierarchies.

Partners

Identify external organizations that exchange or depend on NDC-related information.

KEY OUTPUT

NDC12 Enterprise Impact Assessment

This should show:

- affected systems,
- affected processes,
- affected departments,
- external dependencies,
- risks,
- readiness gaps.

7. Stage 3: Design the Future State

Once the current state is understood, organizations must define how NDC12 should operate in the future.

This is where many critical business decisions are made.

The program should define:

Product Identity Model

How will NDC12 relate to existing identifiers?

Master Data Ownership

Which system owns the authoritative NDC12 record?

Conversion Rules

How will legacy identifiers be linked to future values?

Historical Data Strategy

How will older transactions remain searchable and reportable?

Partner Exchange Rules

Which identifiers will be exchanged with specific partners?

Transition Rules

How will systems behave while multiple identifier formats coexist?

KEY OUTPUT

NDC12 Future-State Design

Technology remediation should begin only after these core rules are sufficiently defined.

8. Stage 4: Build the Integrated Implementation Plan

Each function may have its own activities, but they must ultimately roll into one integrated roadmap.

A strong NDC12 plan should identify:

- Workstreams
- Activities
- Owners
- Start dates
- Completion dates
- Dependencies
- Decisions
- Vendor milestones

- Testing windows
- Regulatory milestones
- Product or portfolio waves

The roadmap should make dependencies visible.

For example:

Master data design must be completed before several system builds.

A serialization vendor upgrade may be required before integration testing.

Labeling changes may depend on regulatory and system readiness.

Trading-partner testing may depend on both companies reaching specific milestones.

A disconnected set of departmental plans is not enough.

KEY OUTPUT

Integrated NDC12 Master Plan

9. Stage 5: Execute by Workstream

Once design and planning are sufficiently mature, implementation can proceed.

Typical workstreams may include:

Regulatory

Regulatory records, requirements, and coordination.

Data

Product master data, identifier mappings, governance, and migration.

Technology

Applications, interfaces, middleware, reporting, and integrations.

Labeling and Packaging

Artwork, barcode updates, packaging changes, and inventory strategy.

Supply Chain

Warehousing, distribution, order management, returns, and external logistics.

Finance and Commercial

Pricing, billing, chargebacks, rebates, contracting, customer data, and reporting.

Partner Readiness

Trading-partner communication, vendor releases, testing, and transition.

Quality and Validation

System validation, procedure changes, controls, and documentation.

Each workstream should maintain its own detailed plan while reporting into the central program.

10. Stage 6: Validate End to End

System-level testing is necessary.

It is not sufficient.

NDC12 should be validated through complete business scenarios.

One example might be:

**Product created product master established regulatory data aligned label produced
barcode generated product manufactured serialized inventory received
customer order processed product shipped wholesaler receives data invoice
generated financial transaction reconciled**

The purpose is to validate the **flow of product identity across departments and organizations**.

Testing should include:

Positive scenarios

Expected transactions using the correct future-state identifiers.

Mixed-format scenarios

One system or partner uses a legacy representation while another uses the future format.

Historical scenarios

A transaction created before migration is processed or reviewed afterward.

Exception scenarios

Incorrect, missing, duplicated, or unexpected identifiers.

Partner scenarios

External systems exchange and correctly interpret product information.

KEY OUTPUT

NDC12 End-to-End Validation and Readiness Report

11. Stage 7: Manage the Transition

The effective date should not be treated as the end of the program.

It begins a transition operating period.

Organizations may need to manage:

- legacy inventory,
- new inventory,
- old labels,
- new labels,
- historical transactions,
- dual-format systems,

- partner exceptions,
- late vendor transitions,
- customer questions.

A formal cutover plan should define:

Cutover Strategy

What changes when, and in which sequence?

Business Continuity

How will critical operations continue if an issue occurs?

Hypercare

Who monitors transactions immediately after major milestones?

Exception Management

How will mismatches be identified, escalated, and corrected?

Transition Metrics

What indicators demonstrate that the new environment is functioning correctly?

12. Building an NDC12 Governance Structure



Because NDC12 crosses so many teams, governance should be explicit.

A practical model includes three levels.

Executive Steering Committee

Provides strategic oversight.

Typical responsibilities:

- approve major decisions,
- resolve cross-functional conflicts,
- monitor enterprise risks,
- ensure sufficient resources.

Central Program Team

Coordinates execution.

Typical responsibilities:

- maintain the integrated roadmap,
- manage risks and dependencies,
- coordinate workstreams,
- maintain decision logs,
- track partner readiness,
- report status.

Functional Workstreams

Own detailed execution.

Potential workstreams:

- Regulatory
- Information Technology
- Data
- Supply Chain
- Packaging
- Finance
- Commercial
- Quality
- Partner Readiness

This structure prevents the initiative from becoming fragmented across departments.

13. Decision Management Is as Important as Project Management

One of the most overlooked aspects of a cross-functional transformation is decision management.

NDC12 will create questions that cannot be resolved through task tracking alone.

Examples include:

- Which system becomes the authoritative product source?
- Who owns identifier crosswalks?
- How long should historical values remain active?
- Which representation should be sent to each partner?
- How should old inventory be treated?
- Which changes require validation?
- When is a product considered transitioned?

These decisions should be documented centrally.

A structured **decision register** should contain:

- Decision required
- Decision owner
- Supporting functions
- Deadline
- Dependencies
- Final decision

- Rationale
- Impacted systems or processes

Unresolved decisions are often hidden schedule risks.

14. Risk Management for NDC12

An enterprise NDC12 program should maintain a central risk register.

Key risk categories may include:

Governance Risk

No clear enterprise owner.

Data Risk

Inconsistent identifier mappings across systems.

Technology Risk

A critical application cannot support the required future state.

Timeline Risk

A vendor upgrade arrives later than required.

Partner Risk

An external organization follows a different transition timeline.

Financial Risk

Billing, pricing, rebates, chargebacks, or reporting are disrupted.

Supply Chain Risk

Product or barcode data does not match inventory or distribution systems.

Regulatory Risk

Implementation does not align with regulatory requirements.

Validation Risk

The organization tests systems individually but misses end-to-end failures.

Risks should be assessed by:

Probability × Business Impact × Time Sensitivity

This allows leadership to prioritize remediation objectively.

15. How to Measure NDC12 Readiness

Readiness should not be defined simply by percentage of tasks completed.

A better approach measures capability.

Examples include:

Governance Readiness

Are owners and decision rights established?

Process Readiness

Have affected business processes been assessed and remediated?

Data Readiness

Are product-identity rules and crosswalks defined?

System Readiness

Can critical applications support the future state?

Partner Readiness

Have major external dependencies been confirmed and tested?

Validation Readiness

Have end-to-end business scenarios passed?

Operational Readiness

Are procedures, training, cutover plans, and support models ready?

This creates an enterprise **NDC12 Readiness Scorecard**.

16. A Practical NDC12 Program Timeline

The regulatory runway creates an opportunity to sequence work deliberately.

Phase 1: Mobilization and Assessment

Establish governance.

Map dependencies.

Identify risks.

Prioritize high-impact areas.

Phase 2: Future-State Design

Define data governance, identifier relationships, system architecture, operating rules, and transition principles.

Phase 3: Remediation

Update systems, processes, data models, labels, interfaces, and procedures.

Phase 4: Integration and Partner Testing

Validate processes across departments and external organizations.

Phase 5: Operational Readiness

Train users, complete cutover planning, confirm support structures, and resolve outstanding issues.

Phase 6: Transition and Hypercare

Monitor execution, manage exceptions, and progressively retire legacy processes when appropriate.

The exact timeline will vary by portfolio size, system landscape, organizational complexity, and external dependencies.

The important point is to work backward from required readiness rather than from the regulatory deadline alone.

17. The NDC12 Program Readiness Checklist

Governance

- Executive sponsor appointed
- Program owner appointed
- Steering committee established
- Functional leads identified
- Decision rights documented

Assessment

- Systems inventoried
- Processes mapped
- Product data dependencies documented
- External partners identified
- Financial dependencies included
- Risk assessment completed

Future State

- NDC12 product-identity model defined
- NDC11 relationship documented
- GTIN relationship documented
- Master-data ownership defined
- Historical-data approach established

Planning

- Integrated roadmap created
- Dependencies documented
- Resource plan created
- Vendor milestones confirmed
- Partner milestones identified

Execution

- System remediation underway
- Data remediation underway
- Labeling plan established
- Process changes documented
- Standard operating procedures updated

Validation

- End-to-end test scenarios defined
- Partner testing scheduled
- Historical scenarios included
- Exception scenarios included
- Business sign-off defined

Transition

- Cutover plan approved
- Dual-format operating model documented
- Hypercare team defined
- Exception management established
- Readiness reporting active

18. Where Organizations Commonly Struggle

The NDC12 transition is likely to expose several recurring organizational challenges.

"IT is handling it."

Technology remediation begins before business requirements are fully understood.

"Regulatory owns it."

Regulatory Affairs monitors compliance while downstream operational dependencies remain undiscovered.

"Every department has a plan."

Functional plans exist but are not integrated.

"We still have years."

Foundational decisions and vendor dependencies are postponed because the deadline appears distant.

"We'll test once the systems are ready."

End-to-end dependencies are discovered late.

"Our partners will tell us what they need."

External dependencies remain unmanaged until close to transition.

These are program-management problems.

They require a program-management solution.

19. How Supply Chain Wizard Can Help

NDC12 requires organizations to connect regulatory understanding with data, technology, operations, commercial processes, and external partners.

Supply Chain Wizard can support pharmaceutical companies in structuring and executing that journey through an **NDC12 Readiness and Transformation Program**.

Our approach can support organizations across the full lifecycle:

- Enterprise NDC12 impact assessment
- Cross-functional readiness workshops
- Program governance and operating model design

- System and process dependency mapping
- NDC10, NDC11, NDC12, and GTIN data mapping
- Master-data governance design
- Integrated implementation roadmap development
- Functional workstream planning
- Vendor and trading-partner coordination
- Risk and decision management
- End-to-end test scenario development
- Validation and operational readiness planning
- Cutover and transition management
- Program Management Office support

Rather than asking each department to independently determine what NDC12 means for them, the program creates **one enterprise view of readiness, dependencies, decisions, and execution.**

20. The Supply Chain Wizard NDC12 Program Model

A practical engagement can be structured into four phases.

Phase 1: Assess

Understand the current state.

Outputs may include:

- Enterprise impact map
- System inventory
- Process dependency map
- Business-function assessment
- Partner inventory
- Risk register
- Initial readiness score

Phase 2: Design

Define the future state.

Outputs may include:

- Product-identity strategy
- Data governance model
- Target operating model
- Governance structure
- Decision framework
- Transition principles

Phase 3: Plan

Build the integrated execution roadmap.

Outputs may include:

- Master program plan

- Workstream plans
- Resource requirements
- Partner roadmap
- Testing strategy
- Risk mitigation plan

Phase 4: Execute and Govern

Support implementation through structured program management.

Outputs may include:

- Program Management Office governance
- Executive dashboards
- Risk and issue management
- Decision tracking
- Partner coordination
- Readiness assessments
- Integrated testing
- Cutover support

The goal is not to replace existing internal teams.

It is to provide the structure that allows those teams to work together effectively.

21. Questions Leadership Should Ask Now

Executives should be able to answer:

- 1 Who owns NDC12 across the enterprise?
- 2 Which departments are already involved, and which are missing?
- 3 Have we mapped every major system and business process that uses NDC data?
- 4 Do we understand our NDC10, NDC11, NDC12, and GTIN dependencies?
- 5 What decisions need to be made before system remediation starts?
- 6 Which external partners could delay our readiness?
- 7 Do functional implementation plans roll into one enterprise roadmap?
- 8 How are risks and decisions being tracked?
- 9 How will we test NDC12 from product creation through downstream transactions?
- 10 How will leadership know when the organization is truly ready?

If these questions produce different answers from different departments, the organization needs stronger program governance.

Conclusion

NDC12 is a defined regulatory change.

Executing it successfully is an organizational challenge.

Pharmaceutical companies must coordinate product data, systems, labeling, supply chain processes, financial workflows, commercial operations, regulatory activities, quality requirements, and external partners.

That coordination does not happen automatically.

It requires:

Ownership.

Governance.

A common roadmap.

Managed dependencies.

Clear decisions.

Integrated testing.

Disciplined execution.

The most important NDC12 question for pharmaceutical leaders is therefore no longer:

"Which systems need to support 12 digits?"

It is:

"How will we coordinate the entire organization and our partners so the business is ready when those 12 digits arrive?"

Organizations that answer that question early can use the available runway strategically, spreading work across manageable phases and reducing transition risk.

Organizations that wait may find themselves attempting to coordinate years of cross-functional dependencies under deadline pressure.

NDC12 is not one project. It is a program.

And successful programs need a plan.

Start with an NDC12 Enterprise Readiness Assessment

Supply Chain Wizard can help pharmaceutical companies establish a structured starting point for NDC12 planning.

The assessment can identify:

- affected departments,
- impacted systems,
- process dependencies,
- data and identifier risks,
- partner dependencies,
- ownership gaps,

- major decisions,
- readiness maturity,
- priority actions.

The result is an actionable **NDC12 Enterprise Readiness Roadmap** that gives leadership one view of what needs to happen, who needs to own it, and how the organization can move from awareness to execution.

Plan the program before managing the deadline.