



TRANSFORMING LIFE SCIENCES

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Beyond Pedigree:
*Ensuring Product and Brand
Security*

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Agenda

 Background/Context	10 min
• Assessment Framework	20 min
• Comprehensive Brand Security Platform	15 min
• Q & A	15 min

The Problem

In the pharmaceutical industry, protecting your brand and your “market” means protecting patient safety...

- Counterfeiting:
 - An illegal, unauthorized imitation, copy, or reproduction of the original branded product, not manufactured or sourced by the brand owner.
 - Unauthorized production and/or packaging of the original branded product.
 - Medicine that is “deliberately and fraudulently mislabeled with respect to identity and/or source”
- Diversion:
 - The process of moving genuine branded product from intended channels to unintended or unauthorized channels of distribution.
 - Rarely a criminal activity – primarily a contractual violation.
 - Can be driven by global or channel price variations, and aggravated by the actions of the brand owner.
- Other Financial/Business Process Issues:
 - Supply chain visibility
 - Reimbursement fraud
 - Chargeback fraud

The Regulations

Regulations are systemic reactions to macro problems...

- Anti-Counterfeiting/Diversion
Problem: High profile counterfeiting and diversion “incidents”
Examples: FL, CA, US FDA, Turkey, some EU nations
- Reimbursement
Problem: Difficult to manage national health system reimbursement
Examples: Many EU nations, led by Italy, France, Belgium
- Anti-Counterfeiting
Problem: Widespread counterfeiting (Lack of faith that product is real)
Examples: African nations, especially Nigeria

Systemic problems must have systemic solutions...

The Solutions

Technology solutions are available to combat each of the identified regulatory motivations...

- Anti-Counterfeiting/Diversions
 - Chain of custody/track and trace solutions with or without centralized database
 - Product serialization (at one or more packaging levels)
 - Import/Export Controls (Including limits on internet sales)
- Reimbursement
 - Labeling solutions with or without serial numbers
 - Product serialization (at one or more packaging levels)
- Anti-Counterfeiting
 - Overt and/or covert markings
 - Tamper-evident packaging
 - Product authentication

But which solutions are appropriate for my company?

A Comprehensive Approach to Brand Security

The best solution is a comprehensive approach that...

- Ensures the security of the company's product portfolio, ultimately for the benefit and safety of the patient
- Manages risks to the brand by identifying susceptibilities and minimizing them through proactive initiatives
- Secures the brand throughout the supply chain and the distribution channel while identifying opportunities for business value generation

The first step in building the comprehensive approach is to perform a brand security assessment...

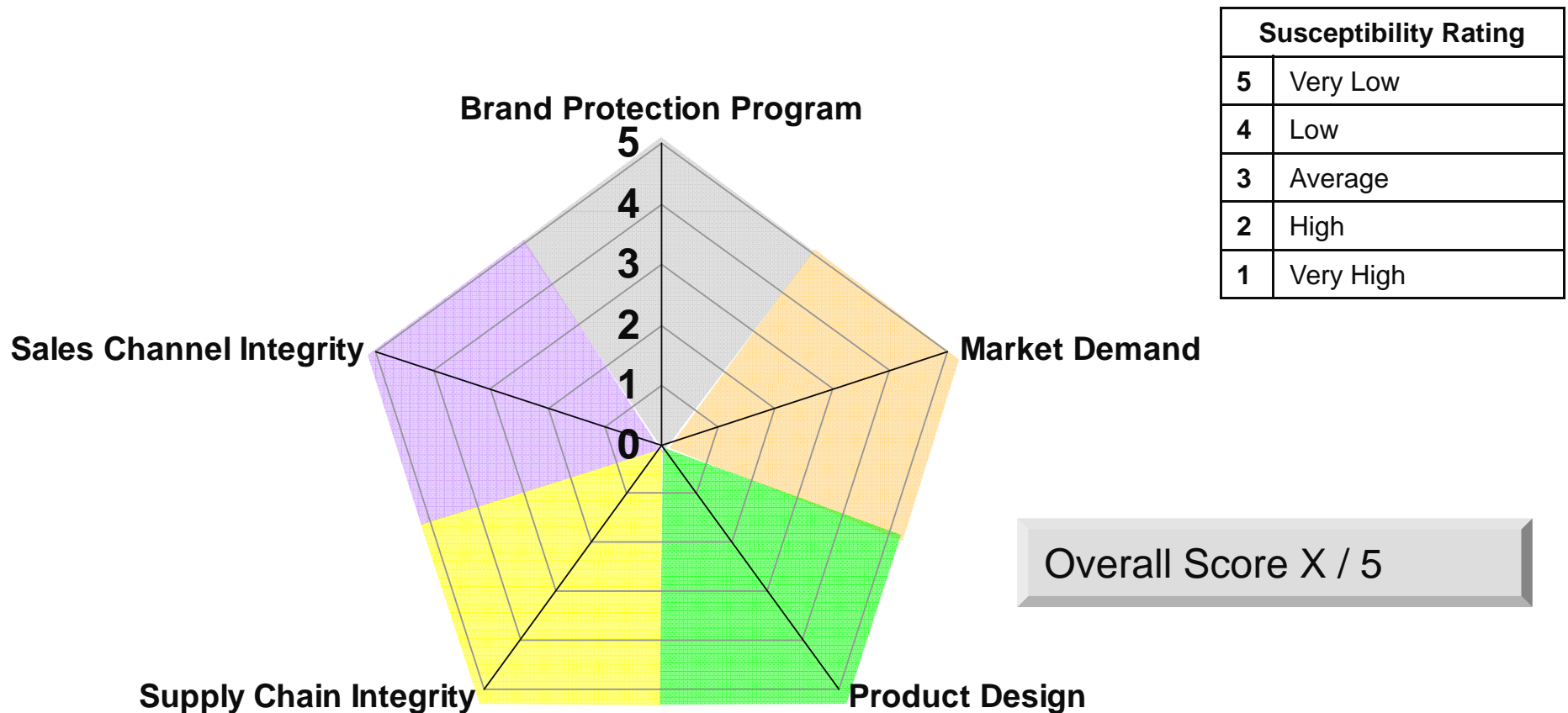


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Brand Security Assessment Framework

Brand security can be evaluated along 5 dimensions...

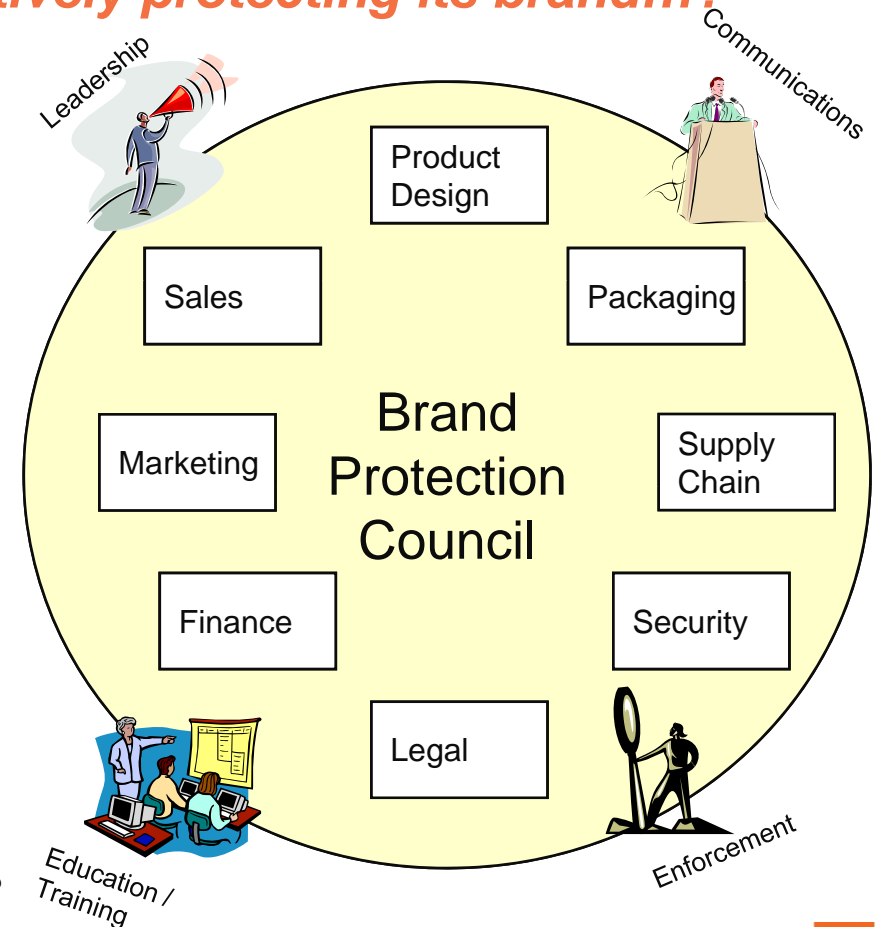


Brand Protection Program Criteria

Brand
Protection
Program

To what extent is the company proactively protecting its brand...?

- Organizational commitment
 - People & functions engaged to focus efforts on protecting the brand?
 - Policies, procedures, code of behavior, protocol and rules of engagement which facilitate best practice?
- Risk-based approach
 - Understanding of susceptibilities from lifecycle perspective?
 - Initiatives in place to focus on highest risk opportunities?
- Awareness
 - Communications and training to align the organization?
- Commitment to outlast all threats
 - Enforcement initiatives?
 - Incentives to align organization and partners?



Proactive brand protection efforts can reduce susceptibility

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Market Demand Criteria

Market
Demand

How is the product positioned and how successful is it...?

- Financial success of product
 - High price/unit? High profit margin?
 - Dominant or substantial market share
 - Premium priced (price leader)?
- Pricing variability
 - For different markets / applications?
 - Domestic & abroad
- Competitive landscape
 - Competitors experience brand pirating?
 - Added value over competitors?
- Public perception of product
 - Heavily advertised? Web activity?
 - Customer “trust” of brand?
- Indications
 - Serious or life threatening disease?
 - Off label uses?
- Product configurations
 - Various strengths/doses/forms?



Opportunity to generate profits also drives illicit activity

Product Design Assessment

Product
Design

How difficult would it be to replicate this product...?

- Physical product appearance
 - Distinctive packaging?
 - Difficult to produce labeling?
 - Unique product appearance?
 - How different are product packaging/labels as strengths of product change?
 - How different are product packaging/labels for different geographic regions?
- Security measures
 - What tamper-evident or closure seal technologies are in place? At what levels in the packaging hierarchy?
 - Are there easy to administer means to authenticate product or product packaging?
 - Are there covert authentication features?
 - Are there means to track product overtly? Covertly?
- Sourcing of container/packaging/labeling materials
 - Where produced?
 - How many sources of supply?



Proactive investments in package/label design can reduce risk



Supply Chain Integrity Criteria

Supply
Chain
Integrity

How resilient is the supply chain to illicit activity...?

- Oversight, control and ownership of key steps in the production process
 - API generation
 - Packaging
 - Warehousing
- Control of product and materials
 - Sourcing of key components that are identified as distinctive
 - Tracking of trends on consumption and scrap
 - Accountability for variances
- Supply & demand balanced
 - Overages?
 - Shortages?



Trust but verify...global supply chain watch words

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Sales Channel Integrity Criteria

Sales
Channel
Integrity

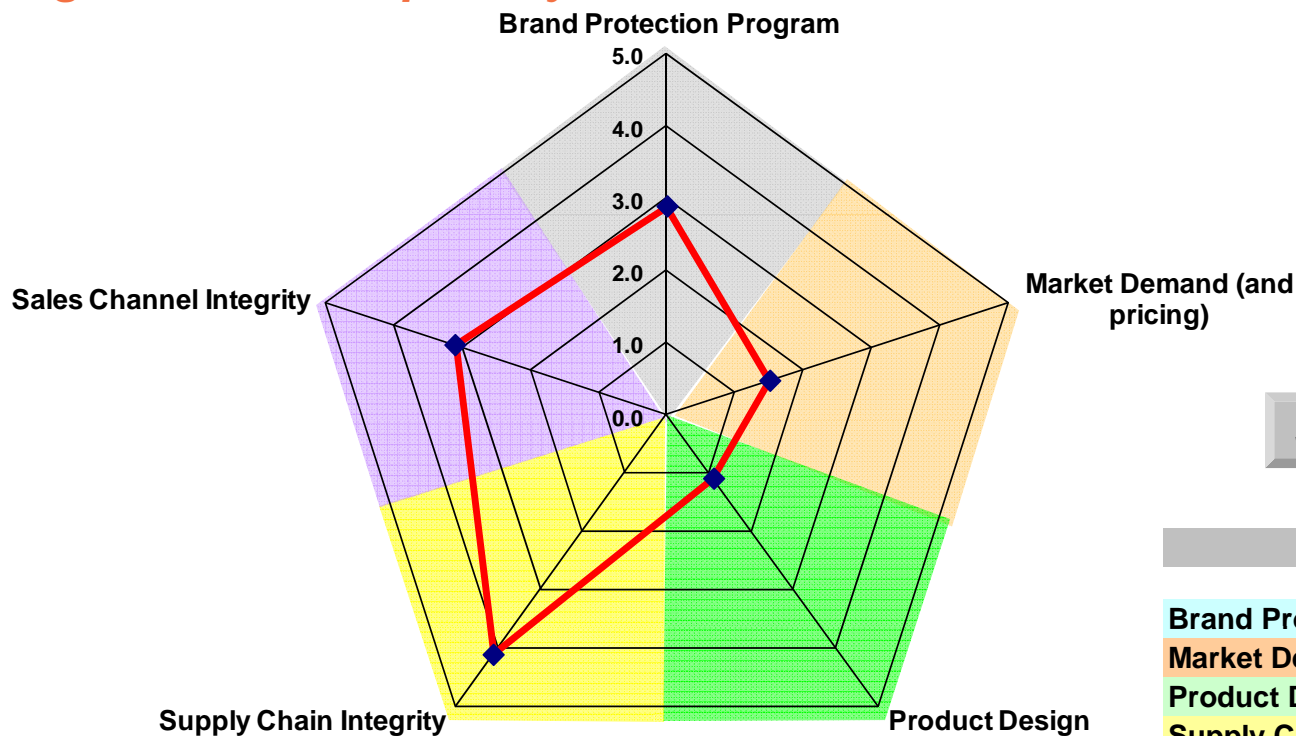
How resilient are the sales channels to illicit activity...?

- Control of distribution
 - Sold direct to customers?
 - Internet availability?
 - Pricing variations by customer segment and/or region?
 - Product variations by strength and dosage form?
 - Product variations by geography?
 - International sites able to transship?
- Scrap/Returns management
 - Process for product validation?
 - Rejects disposal?
 - Returns disposal?
- Supply & demand balanced
 - Excess inventory?
 - Insufficient inventory?



Example: Brand Security Assessment Results

Both market demand and product design showed significant susceptibility...



Susceptibility Rating	
5	Very Low
4	Low
3	Average
2	High
1	Very High


Score 2.5 / 5

Overall Score	2.5
Brand Protection Program	2.9
Market Demand (and pricing)	1.5
Product Design	1.1
Supply Chain Integrity	4.1
Sales Channel Integrity	3.1

...as counterfeiting risk is high (high market demand, high profit), packaging changes are needed to make it harder to counterfeit.



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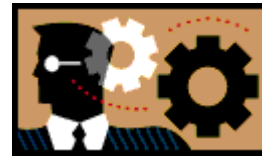
Prescription for Safe and Secure Supply Chain: A Comprehensive Brand Security Platform

Once a thorough assessment of the brand security profile is completed, create the perfect prescription for your company's brand security needs...



• Leadership/Governance

- Security Strategy
- Risk profile/priorities
- Organizational alignment
- Funding
- Implementation planning



• Business Processes

- Requirements Definition
- Re-engineering/Integration
- Policy/Procedures
- Vendor Evaluation
- Sourcing



• Enforcement

- Vulnerabilities
- Event monitoring/management
- Investigations
- Audits/Raids/Prosecutions



• Communications

- Awareness
- Commitment
- Response strategies to events



• Technology

- Security
- Information Systems
- Automation

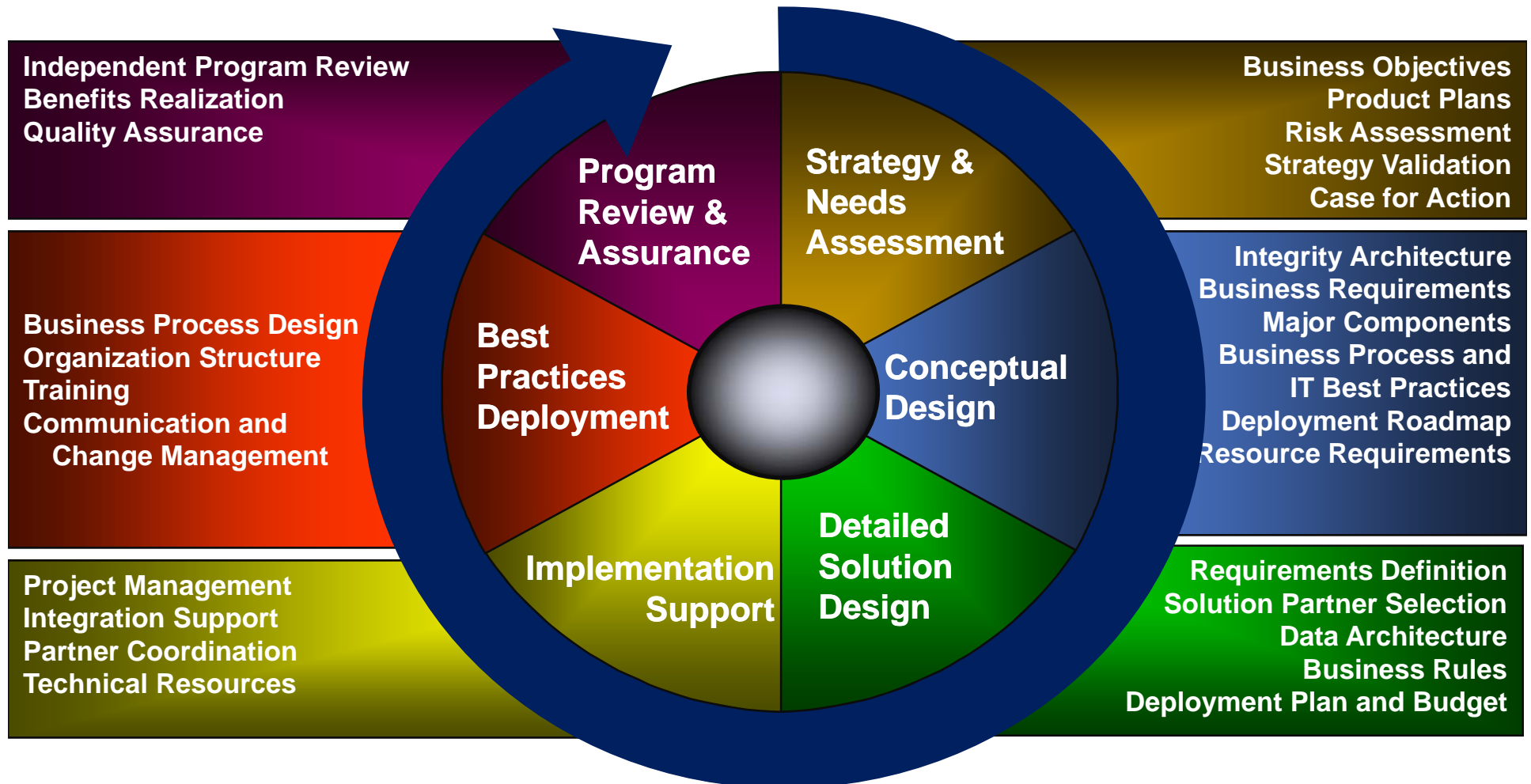


• Education / Training

- Compliance Standards
- Workforce training
- Protocols -- how to tell
- Rules of Engagement

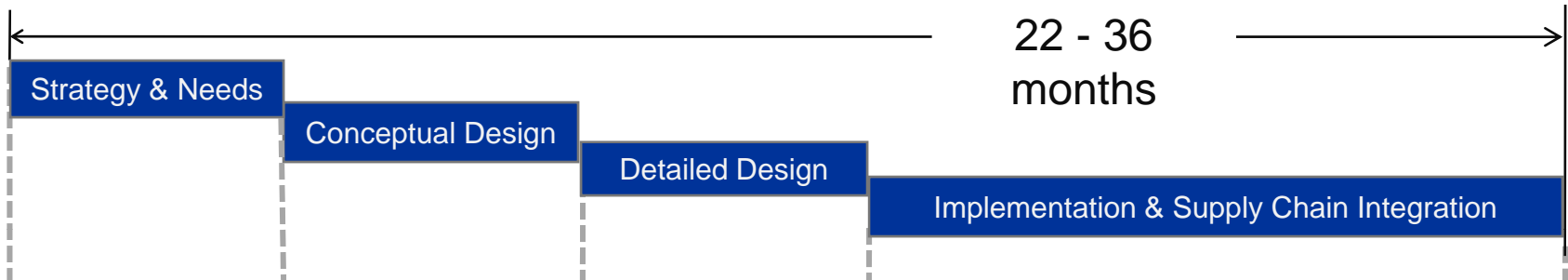
A Comprehensive Brand Security Platform

Then, start the design and implementation...



Brand Security Implementation Timeline

Companies should expect 2-3 years to implement a brand security platform...




	Strategy & Needs	Conceptual Design	Detailed Design	Implementation & Supply Chain Integration		
Major Activities	Strategy & Needs <ul style="list-style-type: none"> • Education • Susceptibility Assessment • Case for Action 	Conceptual Design <ul style="list-style-type: none"> • Assess Packaging Lines, Warehouses and Corporate IT • Business requirements • Approach to brand security • Implementation Roadmap 	Detailed Design <ul style="list-style-type: none"> • Trading partner assessments • Requirements definition • Qualify & Select Vendor • Gap Analysis • Deployment map and budget 	Implementation <ul style="list-style-type: none"> • Equipment selection and installation • System Qualification • EDI connectivity • Pedigree/RxASN implementation • System testing • SOP's • Detailed project plan 	SC Integration <ul style="list-style-type: none"> • EDI data transfers • Testing with trading partners • Personnel training • Monitoring and metrics • "Live" testing 	
Factors Impacting Duration	<ul style="list-style-type: none"> • Product susceptibility • # of products • Understanding of compliance 	<ul style="list-style-type: none"> • Resources • Own vs outsource • CMO & 3PL relationships • Launch activities • Site visits 	<ul style="list-style-type: none"> • # of products • # of packaging lines and 3PL's • Own vs. outsource • Partner commitment • Resources 	<ul style="list-style-type: none"> • Project Management • Integration support • Equipment lead time • Partner readiness • # of products and packaging sites • Resources 	<ul style="list-style-type: none"> • Data carrier technology • Resource availability • # of products and packaging sites • Partner availability • Deadlines 	
Duration	2-4 Months	4-6 Months	6-10 Months	6-8 Months	4-8 Months	

A Multi-Layered Solution

Successful strategies apply a variety of tools...

- Product and Packaging-Focused Solutions
 - Overt brand markings
 - Covert brand markings
 - Embedded security
 - Label graphics
 - Tamper-evident seals
 - Serialization at one or more packaging levels
- Transaction Integrity Solutions
 - Paper Pedigree
 - Electronic Pedigree (Serialized or not)
 - RxASN
 - Digital signature/Certification
 - Product Authentication
- Enforcement
 - Active/Passive tracking
 - Channel management
 - Customer/patient involvement
 - Contingency planning
 - Established governance models

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Questions



Maxiom Group Overview

- Maxiom Group is a business and information technology consulting firm exclusively serving the life sciences industry
- Our clients include emerging, established, and mature Biotechnology, Pharmaceutical, Diagnostic and Medical Device companies
- Maxiom Group helps life science companies transform their strategies, business processes, and business systems to achieve excellence at each stage of their life cycle
 - From drug discovery to clinical development
 - From clinical development to commercial launch
 - From commercial launch to market leadership
- Clients rely on our Focus, Insight and Approach to guide them in transforming their business and in addressing their ongoing business challenges

