

# Implementing an IP Management Process

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**UBM TechInsights**  
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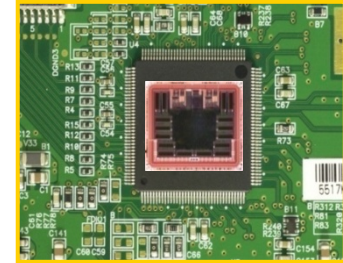
# Agenda

- Introduction and Background
- Medical Device Regulatory Environment
- Product Development Process Overview
- IP Management Process Example
- Questions

# UBM TechInsights Overview

## Professional Services

- Full suite of IP Services, including Patent Portfolio and Asset Management Capabilities, Licensing, Litigation Support, Deposition, Patent Brokerage, Technology Due Diligence, Product/Device Procurement



## Technical Intelligence

- Physical analysis of competitors device/product attributes incl. Circuits, Structures, Materials analysis, Product Teardowns, BoM, IC Costing...



## Business Intelligence

- Design Trends, Business Landscapes and Profiling, Product Distribution and Sales Data, Regional Sales Assessment..

## Software & System Level Analysis

- Source Code, Algorithm Analysis, System Level Testing

## State-of-the-Art Laboratories

- Four world class locations

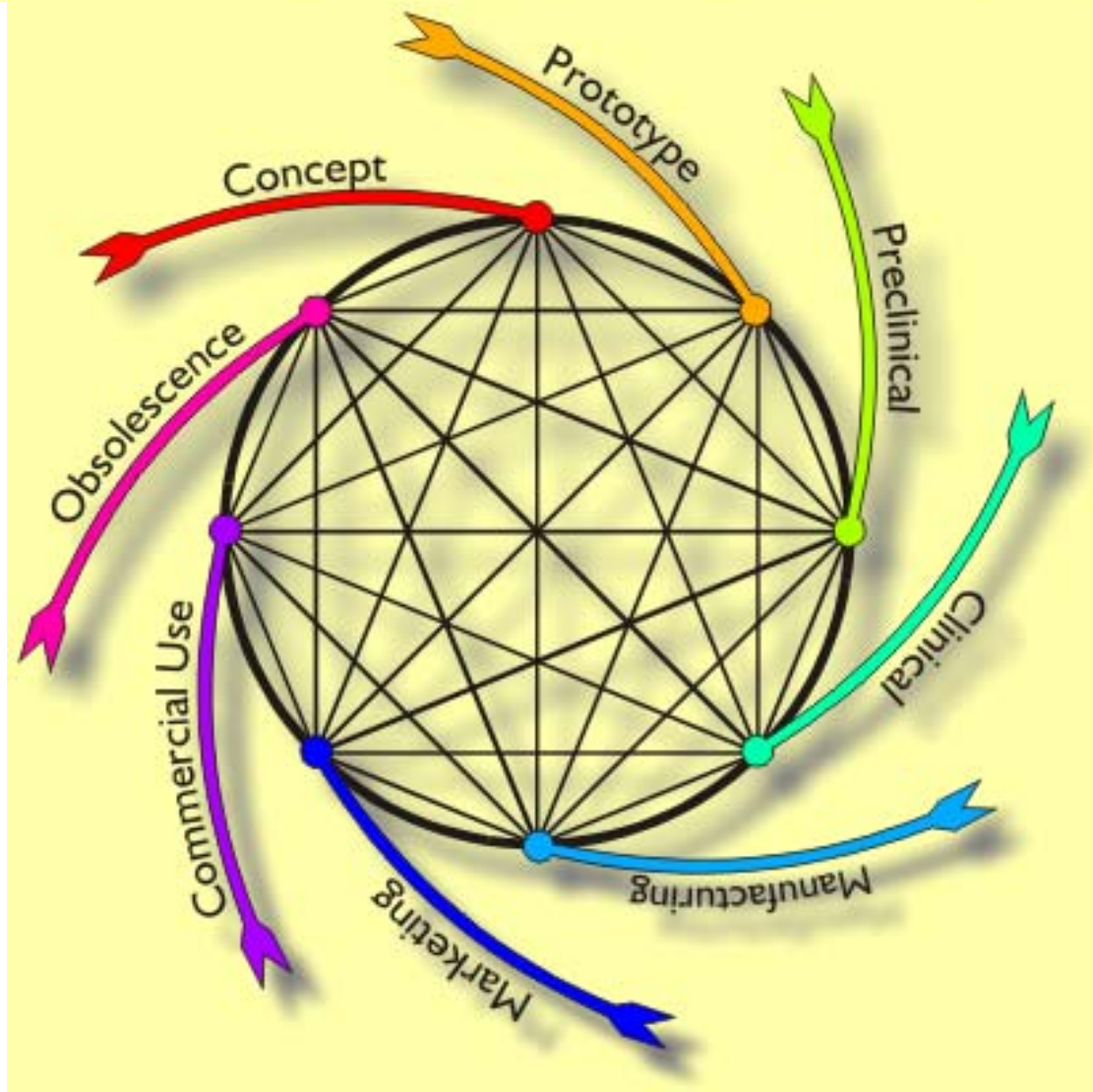


# FDA View of Total Product Life Cycle

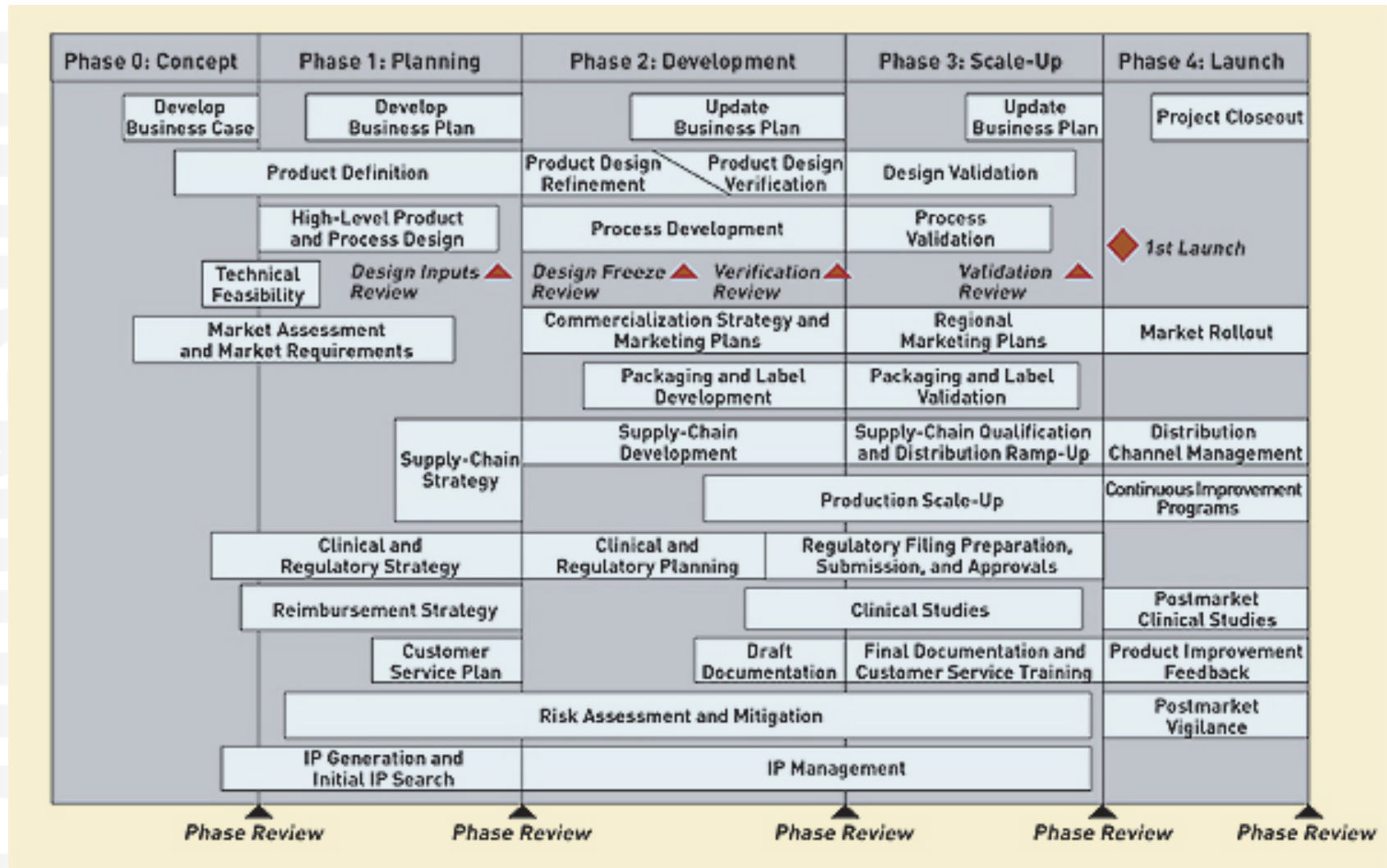
- Represents a design process of iterative product development.
- Incorporates the required interactions between stakeholders and input of every group involved in the development process.
- Focuses on sharing information throughout the different product lifecycle stages and between different departments.
- Encourages the use of Preventive Actions over Corrective Actions.



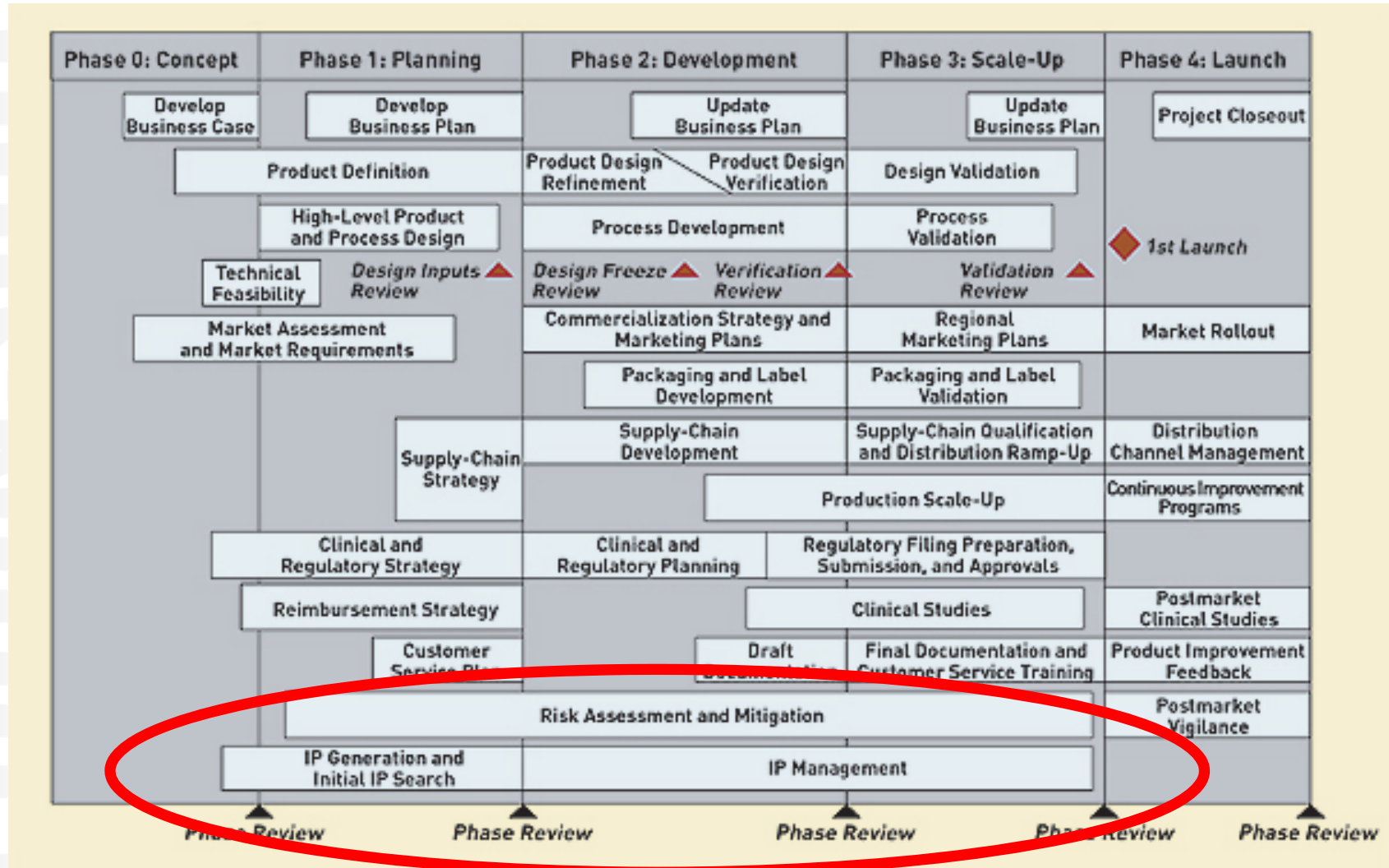
# CDRH Vision - Total Product Life Cycle



# Medical Product Development Process

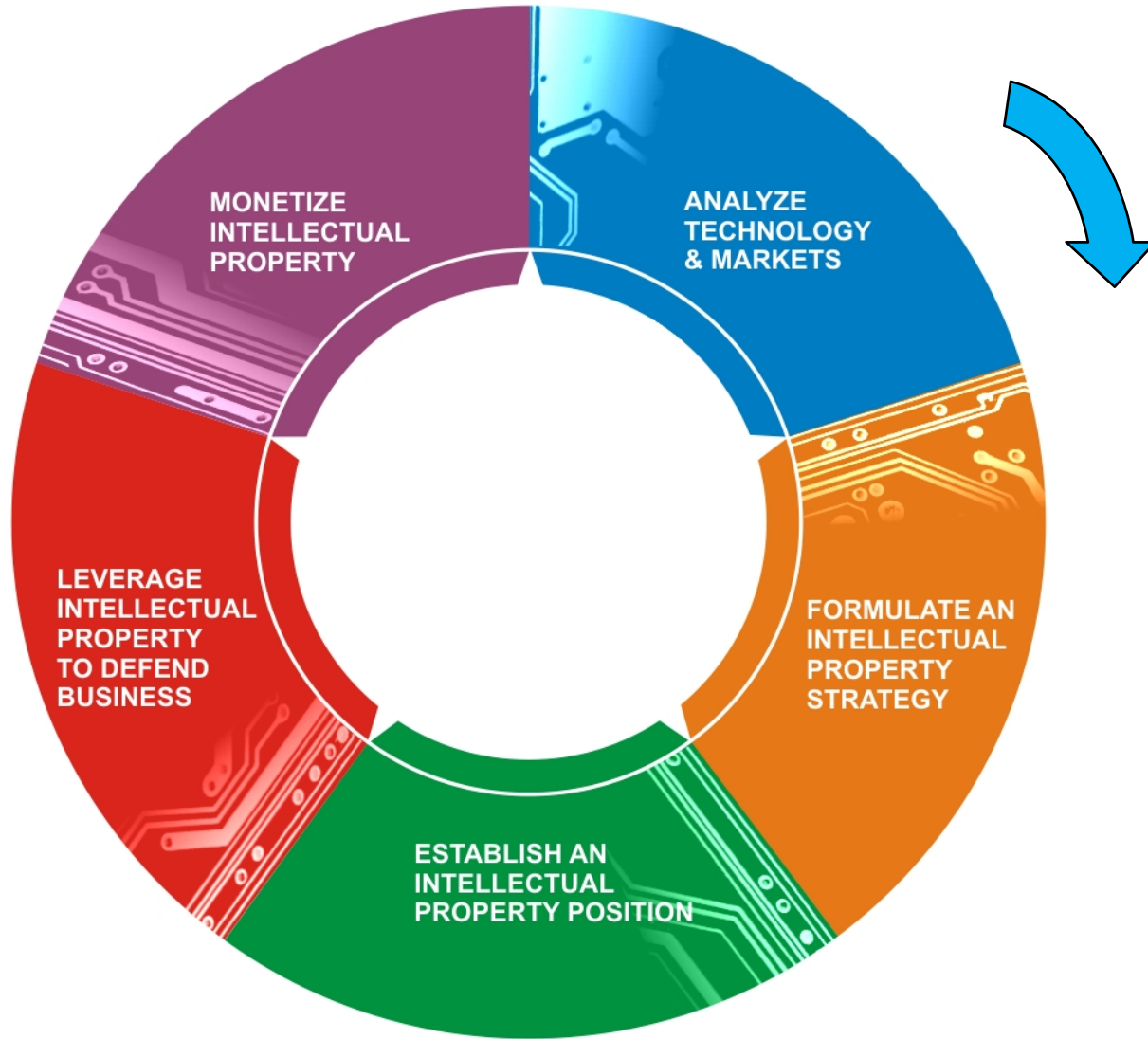


# Medical Product Development Process



# Technology & IP Life Cycle

# Technology & IP Lifecycle



# Organizational IP Objectives

- Increasing business agility by focusing limited R&D resources on IP that matters
- Increasing productivity or competitive edge
- Increasing revenues through new products
- Minimizing IP maintenance costs
- Optimizing IP maintenance “spend” where it matters most
- Divesting unnecessary IP

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# Patent Portfolio Objectives



- Monetize portfolio through
  - Licensing core technology assets
  - Divestment of certain non-core technology assets
- Streamline portfolio: reduce cost (size) and increase quality
  - Cull low-value patents
  - Sell patents not part of core technology or licensing plan

# IP Plan Execution - Organize

- Sort and preliminary review of issued patents
- Identify patent families with US parent or child
- Utilize portfolio management tool
  - Define taxonomy with customer
  - Pre-sort into groups using US class codes to enable assignment according to technology domain
  - Sort patents into taxonomy

# IP Plan Execution - Assess

- Perform preliminary review to assess licensing potential of the assets
- Rank patents according to two criteria:
  - Potential use of the technology in the industry
  - Ability to detect use in end products
- Make Decision
  - Maintain
  - Kill
  - License

# Intellectual Property Program

- An effective IP program can help a company achieve strategic goals in a highly competitive market.
- It can serve as the basis for forging favorable business deals and establishing advantageous competitive positions.
- It can diminish a competitor's business momentum or undermine the confidence of its business partners.
- It can block a competing product's market entry or delay introduction by forcing product redesign.
- It can also impose significant cost disadvantages on the competing product by levying royalties.

# FDA and Medical IP - A Dichotomy

- Patents must show an element of **novelty** (some **new characteristic** which is not known in the **body of existing knowledge** in its technical field).
- An FDA 510(k) application is based on a comparison of your device to another medical device that has already been cleared by the FDA (called the Predicate Device).

**Bottom Line: *Regulatory approval is easiest when stating how much your device is like a previous one.***

# Conclusions

- Companies that fail to employ a rigorous program to protect their IPR run the risk of costly litigation, lost revenue, and weakened market share.
- Technology and IP have a lifecycle just like products.
- The challenge is to understand the complexities of managing and asserting intellectual property rights (IPR) as perhaps the most price-sensitive, fast-moving and competitive market in the world – consumer electronics – meets that of medical devices.

# Questions?

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