



Project
Management
Institute®
New Jersey

Project Management in Healthcare

Life Sciences LCI

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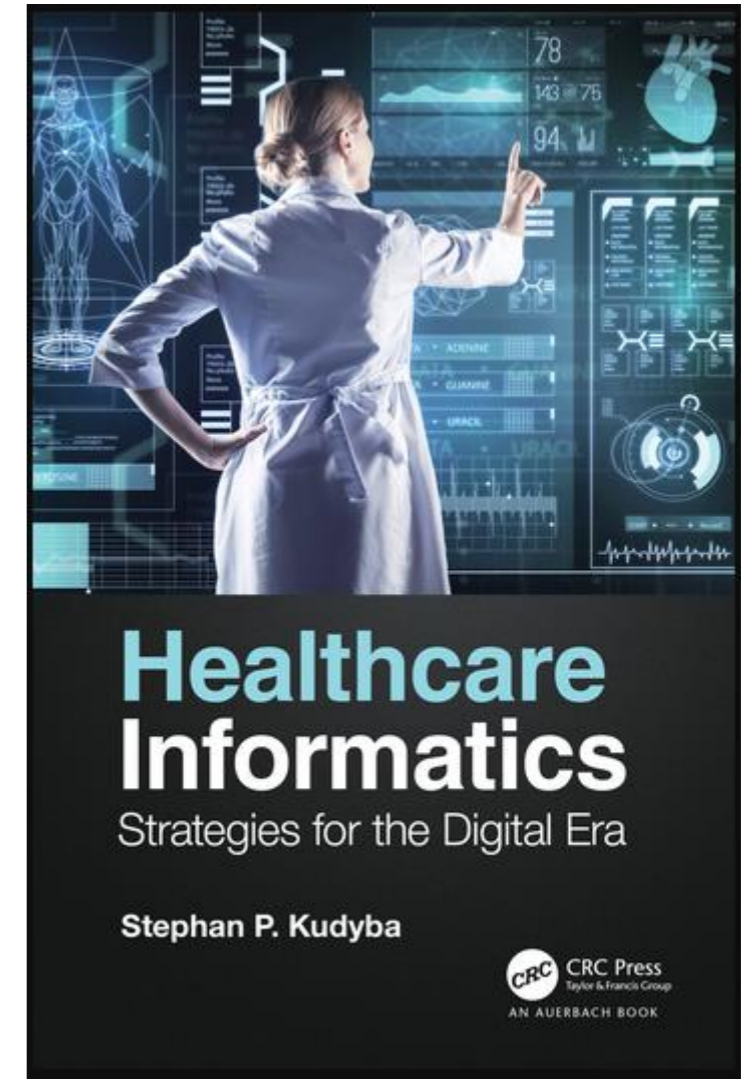
Source...

Adapted from:

Healthcare Informatics, Strategies for the Digital Era

By Stephan P. Kudyba

***Chapter 5 – Project Management in Health Care
by Michael Sarachman***



Overview

- Healthcare methods and processes similar to other industries
- Industry presents unique challenges – and opportunities
 - Business priorities – cost and profitability not always critical
 - Patient care and healthcare provider service often trump other metrics
 - Stakeholder management – power and influence dynamics
 - Risk management – some types of risk to be avoided at all cost
- These aspects make healthcare PM unique
 - Require specific skill sets
 - Influencing can make or break a PM

Project Initiation

Business case

- Role of Financial Metrics
- Compliance and regulatory risk mitigation

Problem Statements

- Define the issue in 1-2 sentences
- Help convey a compelling vision for your project

Organizational Support

- Influential functions – Regulatory Affairs, Quality (Design, Systems, CSV)
- Voice of the customer – commercial and marketing
- Key messages:
 - Improving **patient** outcomes or customer service
 - **Risk** management and mitigation
 - **Quality**
 - **Compliance, compliance, compliance** – especially considering international regulations

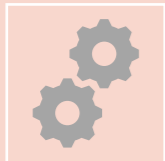
Planning



Agile vs. Waterfall

Agile can be applied, many not ready

- Validation methods can be a barrier



Defining Requirements

Define future state & document requirements

- Used to support validation – design, system or process



Approvals!

The work is not done until it's approved...

Plan must account for this time!

Execution

Testing and Validation

- Standard testing – typically “informal”
- **Validation** – extensive document preparation; structured defect investigations
 - 1 day of development → 3 weeks of validation

Regulatory Impacts

- Product, labeling or manufacturing **changes** → regulatory impacts
- Requires **review** and/or regulator **approval** in some markets
 - May delay implementation or require special controls to segregate changes

User Training

- Must be **completed and documented** before changes go into effect
 - Ranges from “read & acknowledge” to instructor-led or computer-based training

Healthcare-specific Considerations



Thank you!

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