

# The Keys to Cost-Effective Project Management

Chris DeVany, Pinnacle Performance  
Improvement Worldwide

*Sponsored by*  
 **Millstone**



# Objectives

## Detailed information addressing:

- Regulatory requirements
- Understanding regulations like EU MDR
- Working on cross-functional teams
- Cost-efficient design
- Design For Manufacturability
- Supply chain management
- FDA Quality Management System Regulation
- Gaining feedback
- Securing adequate funding
- Developing a comprehensive marketing and market access strategy
- Collecting real-world data

# The 10 Keys To Cost-Effective Project Management



1. Strategic Planning and Project Scoping
2. Regulatory Concerns
3. Cross-Functional Teams and Collaboration
4. Innovation and Cost-Efficient Design
5. Supply Chain Management
6. Quality Assurance and Risk Management
7. Patient and Practitioner Engagement
8. Funding and Financial Management
9. Marketing and Market Access Strategy
10. Continuous Improvement and Post-Market Surveillance

# Strategic Planning And Project Scoping



Before embarking on the development of orthopedic products, perform a thorough market analysis to identify target demographics and understand [regulatory requirements](#). These steps define project goals, budgets and expenses for research, development, regulations, manufacturing and marketing. Detailed project scoping identifies financial risks early in the process, allowing you to implement mitigation strategies.

# Regulatory Requirements



Referencing from BONEZONE<sup>®</sup> a helpful article by Dan Cook, titled:

*OSMA Sets its Sights on OMTEC*, which describes the efforts by the [Orthopaedic Surgical Manufacturers Association](#) (OSMA) to expand its reach and influence in the device development process.

<https://bonezonepub.com/2024/02/22/osma-set-its-sights-on-omtec/>

# Regulatory Concerns



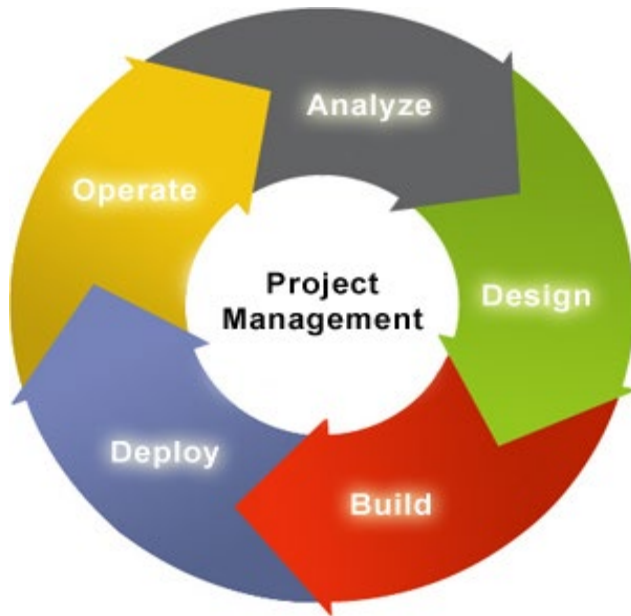
Regulatory strategy and compliance are not just legal obligations. They should be a key part of your strategic plan. Early and continuous engagement with regulatory bodies like FDA and understanding regulations like [EU MDR](#) can streamline the approval process. Developing a product with regulatory requirements in mind leads to fewer costly revisions. Investing in a knowledgeable regulatory affairs team or consultant allows you to navigate these complex processes efficiently, which saves considerable time and resources.



# Regulatory Concerns

## FDA: Overview Of Device Regulation

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>



# Regulatory Concerns

EU MDR: Regulation MDR (EU) 2017-745

<https://tinyurl.com/mw278unz>





# Regulatory Concerns: Taking Action



The transition deadline for device companies to register products under the new MDR has been extended to December 31, 2027 for high-risk devices and December 31, 2028 for medium- and low-risk devices.

However, what are you doing now to meet the EU MDR deadline?

<https://bonezonepub.com/2024/01/08/act-now-to-meet-the-eu-mdr-deadline/>

# Cross-Functional Teams And Collaboration

Orthopedic product development benefits significantly from the integration of cross-functional teams. These teams combine diverse expertise from biomedical engineers, regulatory affairs specialists, quality assurance professionals, sourcing guides, marketing experts and sales strategists.



*Why Cross-Functional Communication Is Key For Success,*  
by Patrick McGuire

<https://bonezonepub.com/2022/05/23/why-cross-functional-communication-is-key-for-success/>

# Cross-Functional Teams And Collaboration



Collaborative problem-solving leads to innovative solutions and a shared sense of accomplishment — factors that are essential in the management of [multigenerational workforces](#) and the hiring of professionals from outside industries who are increasingly contributing to the success of product development projects in orthopedics.

*Why Managing Multigenerational Teams Is A Good Thing,*

**by Patrick McGuire**

<https://bonezonepub.com/2023/11/20/why-managing-multigenerational-teams-is-a-good-thing/>

# Cross-Functional Teams And Collaboration

Embracing this type of diversity in your team and encouraging members to share their unique perspectives and ideas promotes creative critical thinking skills in the face of complex challenges.



# Eight Characteristics of Effective Teams

Effective Teams Have:



1. A Clear and Elevating Goal
2. A Results Driven Structure
3. Competent Team Members
4. Unified Commitment
5. Collaborative Climate
6. Standards of Excellence
7. External Support and Recognition
8. Principled Leadership

# Innovation and Cost-Efficient Design



Advancing orthopedic product development isn't just about producing breakthrough technologies or materials. It also involves cost-efficient design. This means creating products that meet or exceed clinical requirements and patient needs while also being manufacturable at a reasonable cost. Techniques such as Design for Manufacturability (DFM) can significantly reduce production expenses and improve product quality. Additionally, embracing incremental innovation — where existing products are refined and improved — can be a more cost-effective approach than developing entirely new products from scratch.

# Innovation and Cost-Efficient Design

***10 Ways Your Design Could Increase (or Decrease)  
Orthopaedic Manufacturing Costs, by Paragon Medical***

<https://bonezonepub.com/2022/02/16/10-ways-your-design-could-increase-or-decrease-orthopaedic-manufacturing-costs/>

***Design For Manufacturability (DFM): Unlock DFM Benefits:  
A Guide for Product Development Leadership, by Dale Tempco***

<https://bonezonepub.com/2019/05/20/unlock-dfm-benefits-a-guide-for-product-development-leadership/>





# Supply Chain Management



Effective supply chain management is pivotal in controlling costs. For orthopedic products, this involves strategic sourcing of materials, components and services. Develop strong relationships with suppliers and consider long-term contracts to lock in prices and ensure a steady supply.

Additionally, a robust logistics strategy is necessary to minimize shipping costs and delays. Implementing lean manufacturing principles to reduce waste and improve efficiency contributes to lower production costs.

# Supply Chain Management

## ***Expert Insights for Solving Common Orthopedic Supply Chain Challenges, by Patrick McGuire***

<https://bonezonepub.com/2023/06/05/expert-insights-for-solving-common-orthopedic-supply-chain-challenges/>



# Quality Assurance and Risk Management

Quality assurance is non-negotiable in the medical device sector, and proactive quality management can prevent costly recalls or regulatory sanctions. Implementing a comprehensive quality management system (QMS) that complies with ISO 13485 standards is crucial. FDA recently released the Quality Management System Regulation (QMSR) [final rule](#) that outlines new requirements.

Additionally, a robust risk management plan that identifies, assesses and mitigates potential risks throughout the product lifecycle and saves significant resources by preventing issues that can derail projects before they arise.



# Quality Assurance and Risk Management



**“Practical Ways to Comply with FDA’s QMSR Final Rule”  
by Dan Goldstein**

<https://bonezonepub.com/2024/03/26/practical-ways-to-comply-with-fdas-qmsr-final-rule/>

# Patient and Practitioner Engagement



Engaging with end-users — patients and providers — throughout the development process can provide invaluable insights into product design, usability and market demand. This [feedback](#) can guide product refinement, reducing the likelihood of costly post-launch modifications. Moreover, early engagement with the surgical community aids in building advocacy and awareness, smoothing the path to market acceptance and adoption.

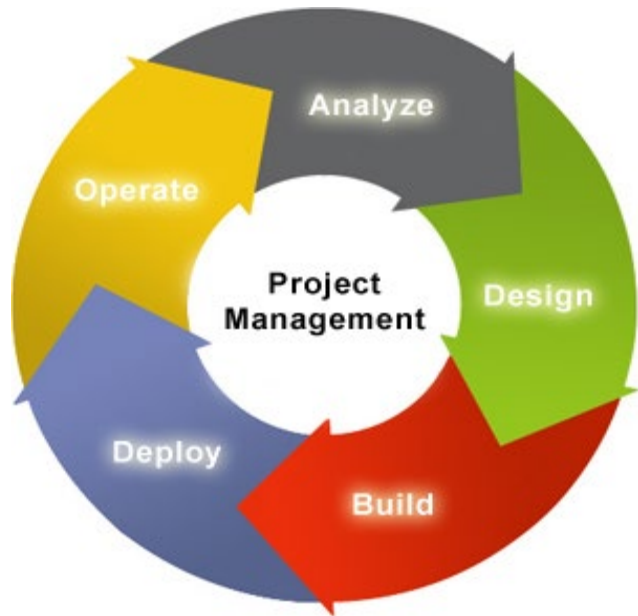
# Patient and Practitioner Engagement



***40+ Orthopedic Surgeons Form Network to Support New Companies and Innovation, by Natalie Shawyer***

<https://bonezonepub.com/2020/01/06/40-orthopedic-surgeons-join-network-to-support-new-technology-and-innovation/>

# Funding and Financial Management



Securing adequate funding is a critical aspect of bringing orthopedic products to market. Exploring various funding sources, including venture capital, grants and partnerships with established companies, provides the financial backing necessary for development and launch.

Effective financial management, with regular budget reviews and cost tracking, ensures that the project stays on track financially. Leveraging financial forecasting tools can also aid in anticipating and planning for future financial needs.



# Patient and Practitioner Engagement



***Orthopedic Funding by Segment and Company,***  
**by BONEZONE Editors**

<https://bonezonepub.com/2023/05/22/orthopedic-funding-by-segment-and-company/>

# Marketing and Market Access Strategy

Developing a comprehensive marketing and market access strategy early in the project lifecycle is essential for a successful launch. This includes identifying key market segments, understanding the competitive landscape and developing a value proposition that resonates with patients and healthcare providers.



Effective branding and targeted marketing campaigns build anticipation and demand, facilitating a smoother market entry. Additionally, negotiating with insurance providers and healthcare systems for product coverage and reimbursement has a significant impact on market success.

# Marketing and Market Access Strategy



## ***6 Best Practices for Successful Product Commercialization,*** **by Heather Tunstall**

<https://bonezonepub.com/2020/04/06/6-best-practices-for-successful-product-development-and-commercialization/>

# Continuous Improvement and Post-Market Surveillance



The product development journey doesn't end with the product launch. Continuous improvement based on post-market surveillance and [real-world data](#) is vital for sustaining success. Collecting and analyzing data on product performance, safety and user satisfaction allows for ongoing enhancements. This not only ensures compliance with regulatory requirements for post-market monitoring but also reinforces the product's value proposition, supporting long-term profitability.

# Continuous Improvement and Post-Market Surveillance



***Building the Pathway to Successful Use of Real-World Evidence (RWE), by Jay Erturan, M.D.***

<https://bonezonepub.com/2024/01/15/building-the-pathway-to-successful-use-of-rwe/>

# Review of the Objectives

Detailed information addressing:

- Regulatory requirements
- Understanding regulations like EU MDR
- Working on cross-functional teams
- Cost-efficient design
- Design For Manufacturability
- Supply chain management
- FDA Quality Management System Regulation
- Gaining feedback
- Securing adequate funding
- Developing a comprehensive marketing and market access strategy
- Collecting real-world data

# Wrapping Up

- Questions
- Thank You
- Be sure to Action Plan



# The Keys To Cost-Effective Project Management

# Thank You

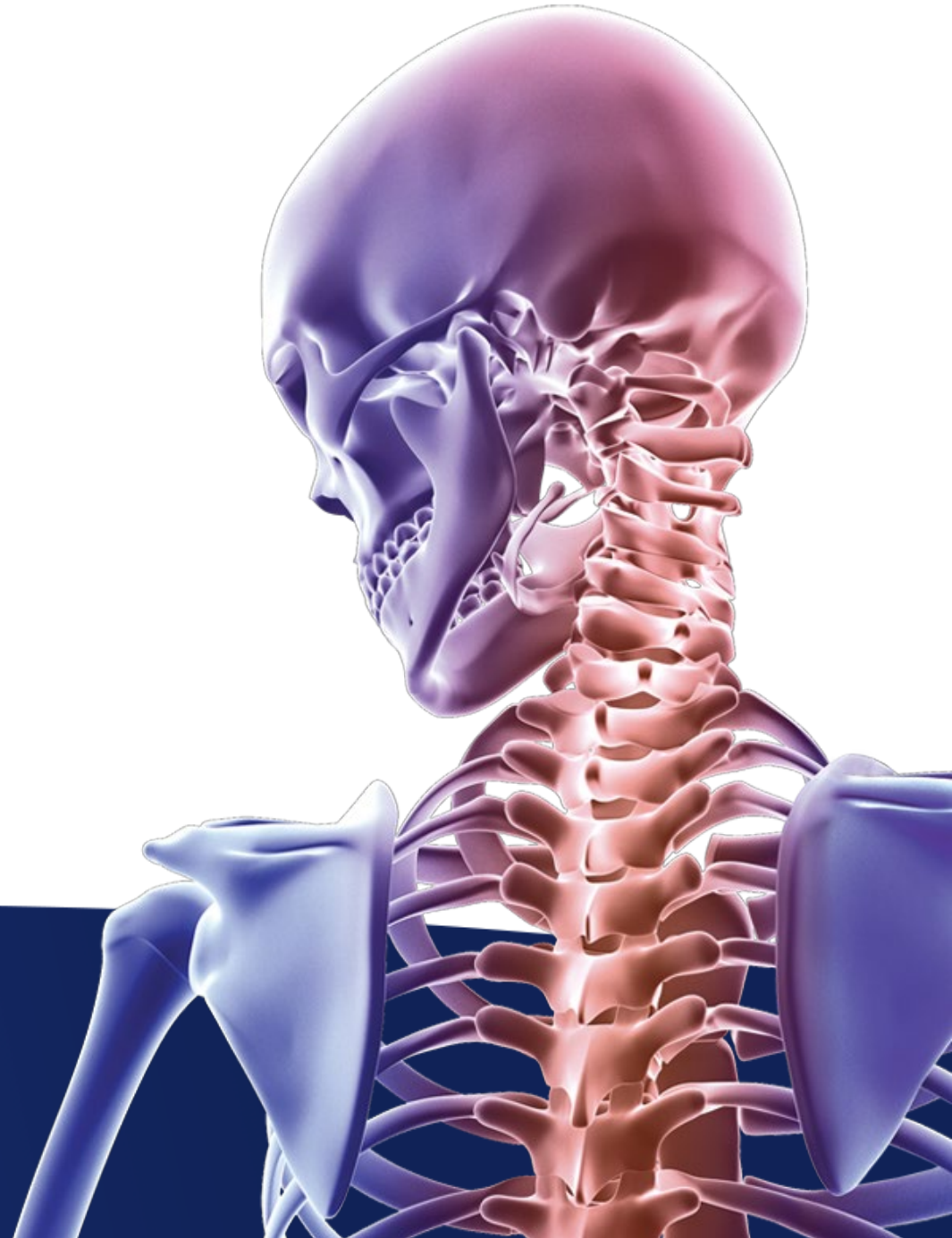
Christopher R. DeVany, PMP

617-308-8070

[cdevany@ppiw.com](mailto:cdevany@ppiw.com)

If you wish to receive our  
Management Tips email newsletter,  
please send an email to [cdevany@ppiw.com](mailto:cdevany@ppiw.com).

 MTEC®



# THANK YOU

Learn more about OMTEC  
at [OMTECexpo.com](http://OMTECexpo.com)

 **OMTEC**<sup>®</sup>

