



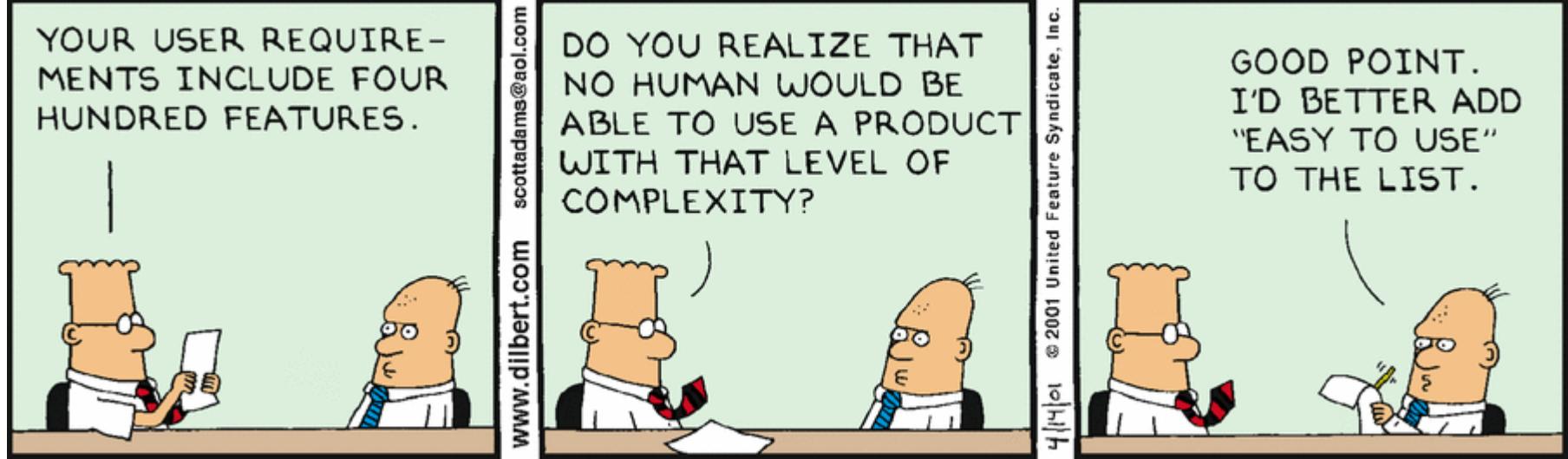
By:  
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**MT&DC's Instructor**

## 5 Top Challenges to Requirements Management



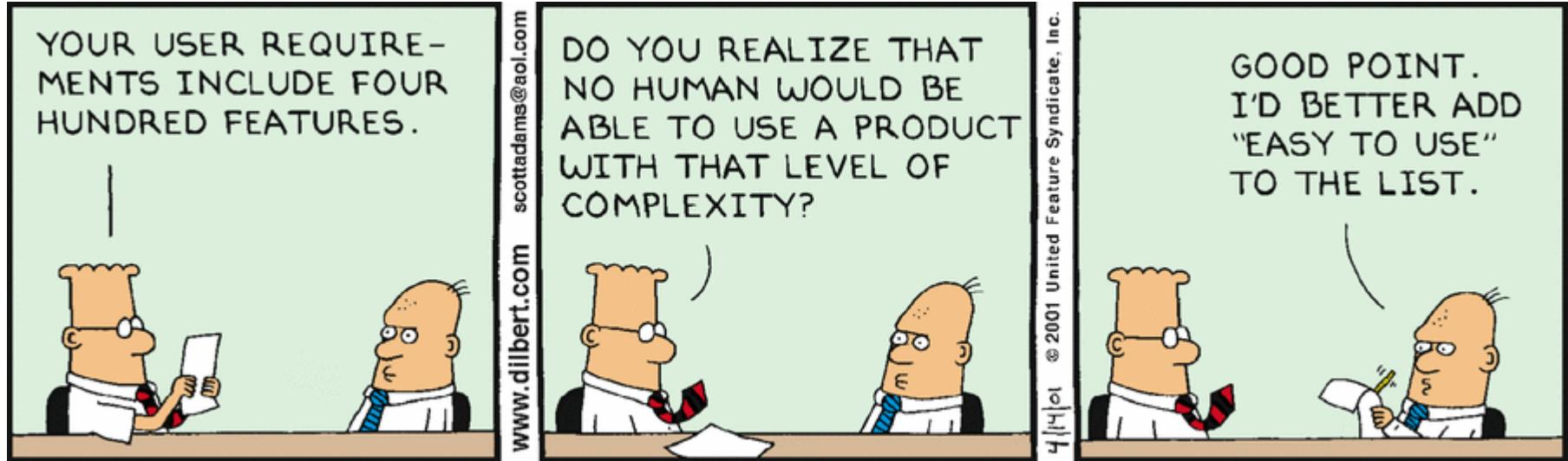


# Is there a difference between a „Requirement” and a „Request”?





# Is there a difference between a „Requirement” and a „Request”?



- Requirements are capabilities that a product must meet to satisfy a user's need to solve a problem.
- Request – Something asked for (yet to be determined as a want or a need).



# 5 Top Challenges to Requirements Management

- # 1: Success criteria is not clearly defined
- # 2: Stakeholders don't know what they want
- # 3: Stakeholder priorities conflict
- # 4: Requirements conflict
- # 5: Requirements management tools





The case study project was: “Bringing an Innovative Device to Market: Premarket Approval (PMA) of Medical Devices”

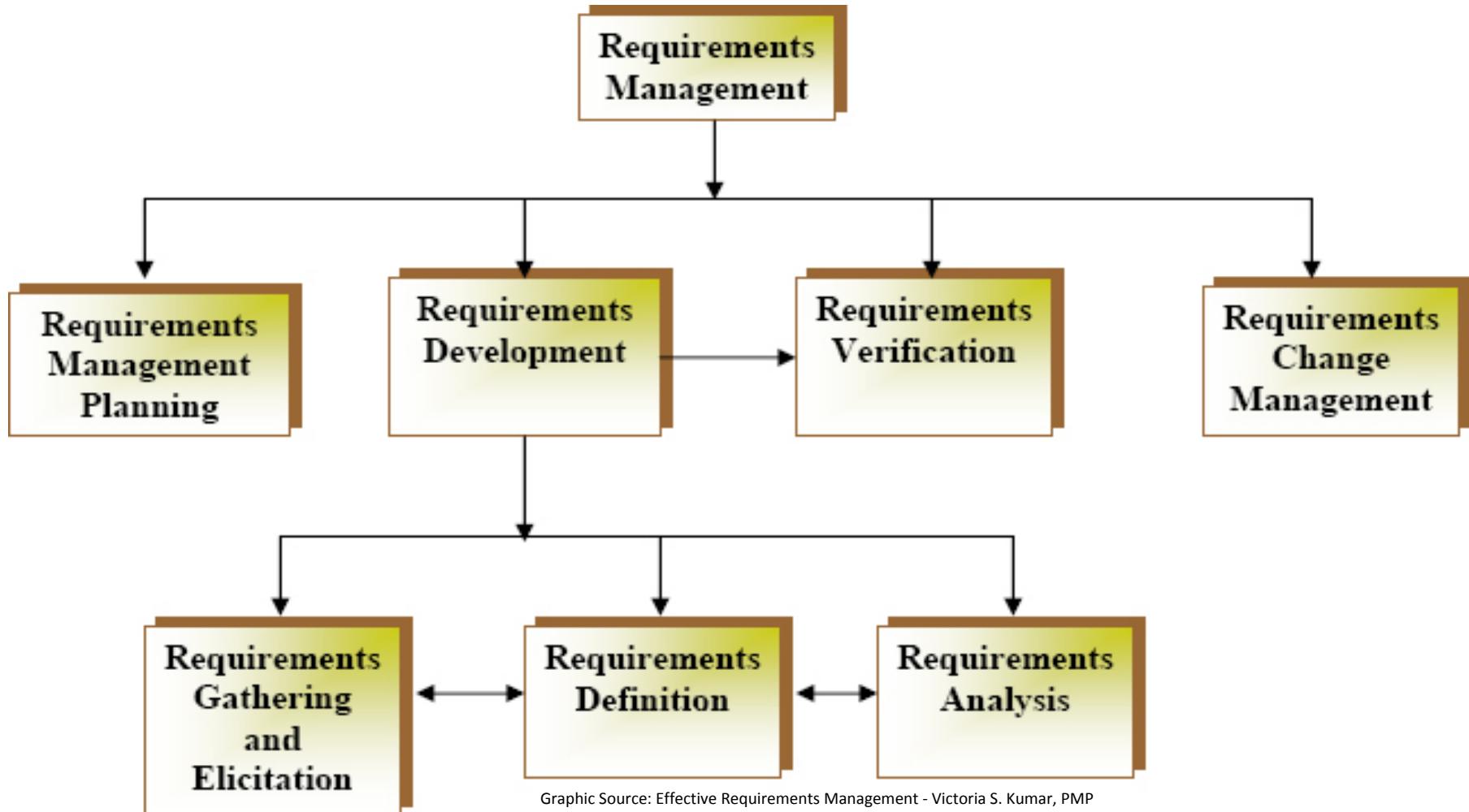
It covered regulatory issues and requirements management challenges, raised when bringing a bare metal coronary stent device to market through the Premarket Approval (PMA) regulatory pathway.

This project’s requirements management issues were based on the need to:

- Introduce the medical device First in Human (FIH) Investigational Device Exemption (IDE) Application
- Introduce the medical device PMA
- Understand the steps to obtain a PMA application and its data requirements
- Examine the general principles of nonclinical and clinical investigations



# 5 Top Challenges to Requirements Management

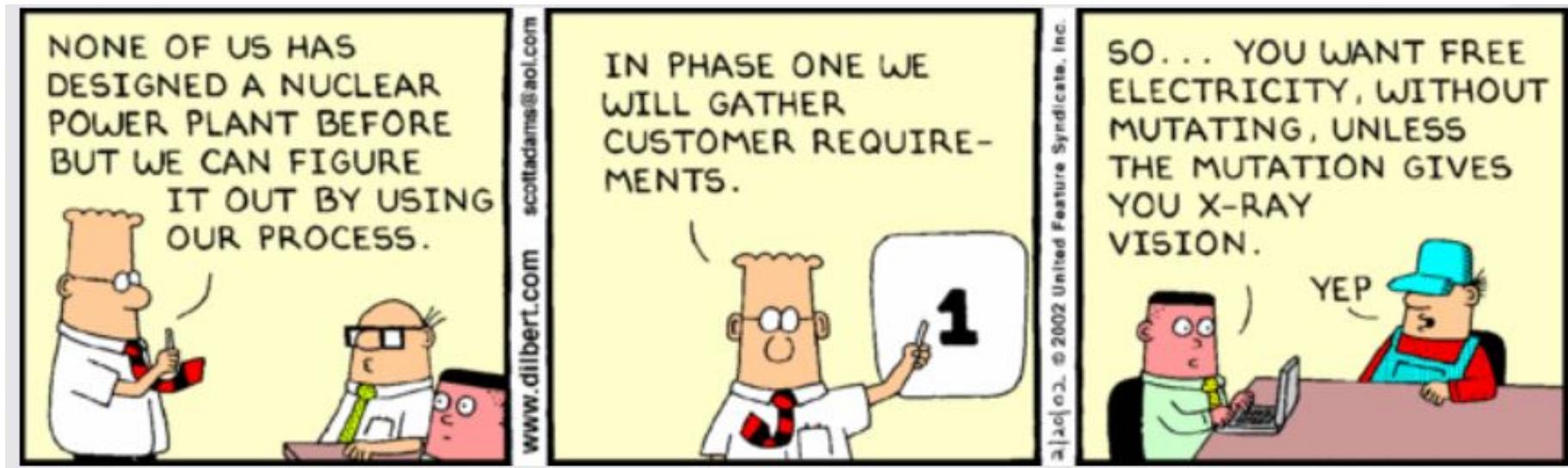


Graphic Source: Effective Requirements Management - Victoria S. Kumar, PMP



# # 1: Success criteria is not clearly defined

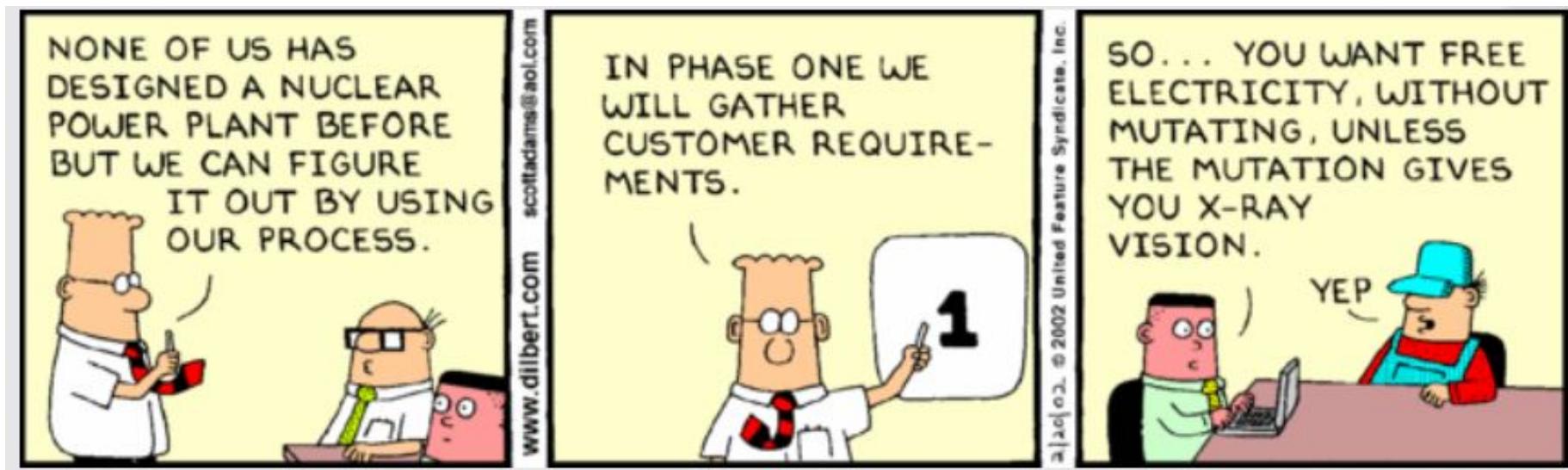
- The challenge of not knowing what your end goal looks like, or what success should have, are key challenges for any requirements gathering and management initiatives.





# # 1: Success criteria is not clearly defined

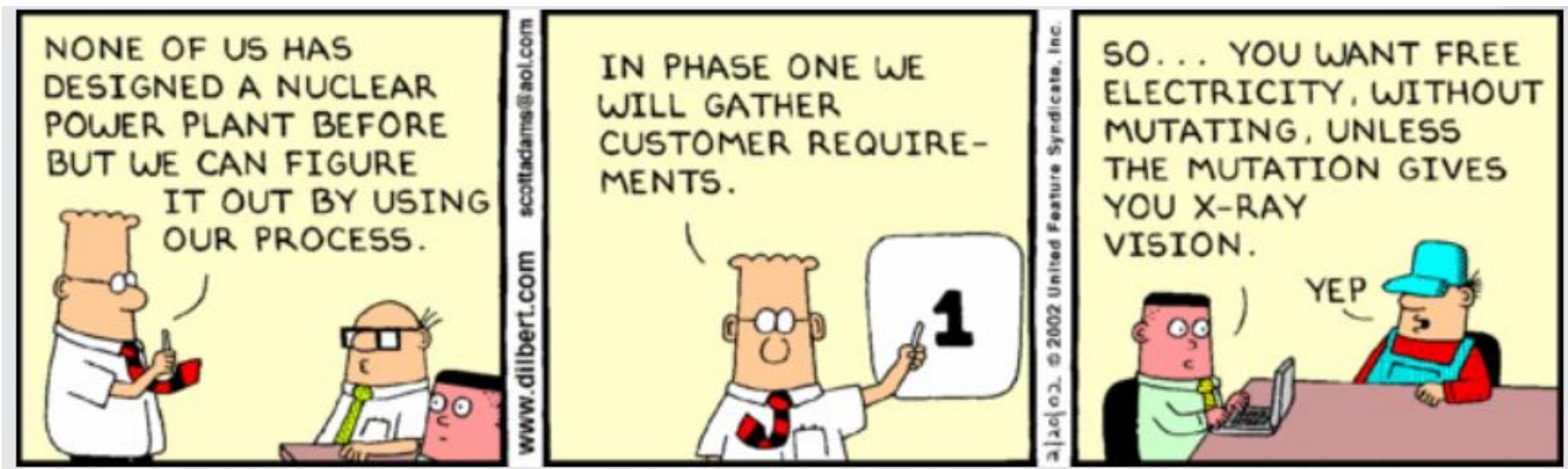
- Getting clear guidance and direction from stakeholders is not easy to do.





# # 1: Success criteria is not clearly defined

- Getting clear guidance and direction from stakeholders is not easy to do.
- The key to addressing this issue is to break the project into smaller pieces, and start from a section that the client is clearer about.





## # 2: Stakeholders don't know what they want

- Stakeholders don't know what they want, but they know what they DON'T want...





## # 3: Stakeholder priorities conflict

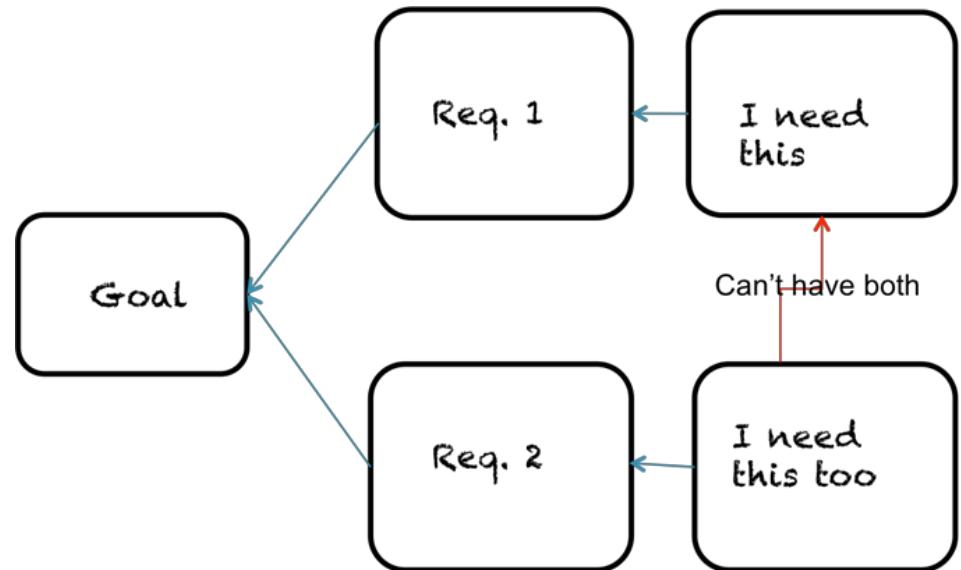
- Not all stakeholders will agree on what should be a top priority; because of this, different requirements will conflict
- Negotiation is a key for this
- Getting to consensus





## # 4: Requirements conflict

- With all the different types of requirements and business strategies changing with every market trend, requirements conflict is common in developing and managing your solution.





## # 5: Requirements management tools

- Having the right tools to help manage requirements is a key to better requirements delivery





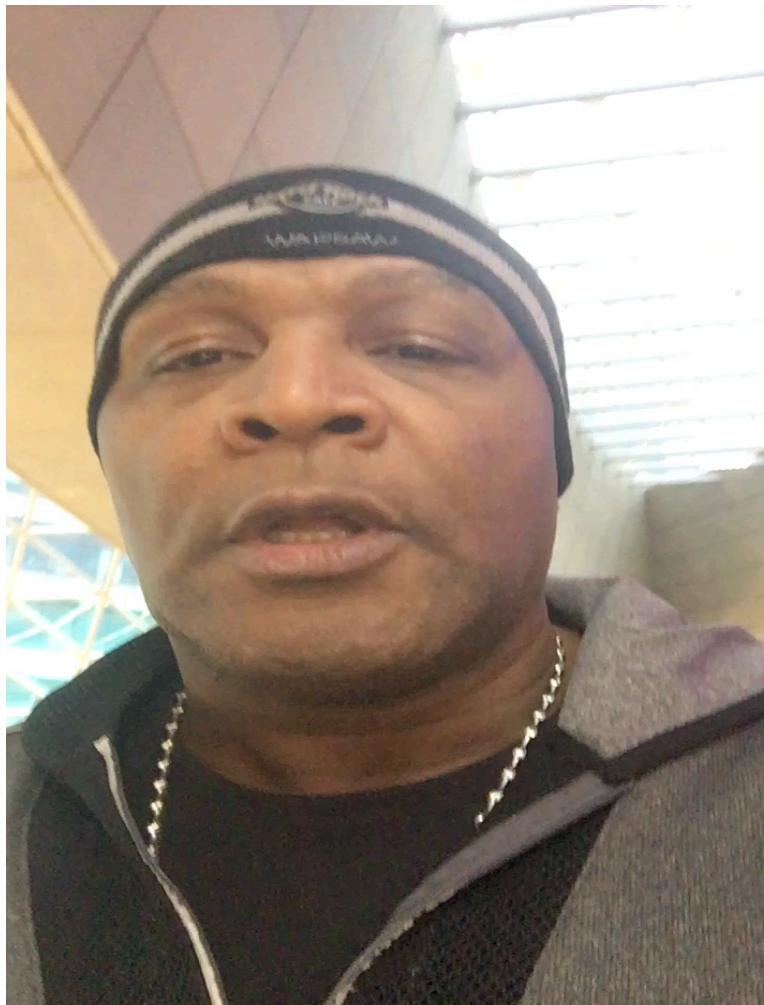
# # 5: Requirements management tools

## ■ What are some RM tools?

- [Agile Manager](#) (2.55) by [Hewlett Packard Enterprise](#)  
Scope: RM, Agile
- [Blueprint](#) (v6.4) by [Blueprint Software Systems, Inc.](#)  
Scope: RD, RM, UI Mockup, Visual Modeling
- [CA Agile Central \(previously: Rally\)](#) (2016.1) by [CA Technologies \(previously: Rally Software Development Corp.\)](#)  
Scope: RM, Agile
- [Caliber](#) (11.4.17) by [Micro Focus](#)  
Scope: RM, Visual Modeling
- [codeBeamer Requirements Management](#) (8.0.1) by [Intland Software GmbH](#)  
Scope: RM
- [Cognition Cockpit](#) (7.4) by [Cognition Corporation](#)  
Scope: RM, Product Management, Testing, Project Management
- [Enterprise Architect](#) (13) by [Sparx Systems](#)  
Scope: Visual Modeling, RM
- [HPE ALM/Quality Center](#) (12.53) by [Hewlett Packard Enterprise](#)  
Scope: RM, Testing, Project Management, Issue Management
- [IBM Rational DOORS](#) (9.6.1.6) by [IBM](#)  
Scope: RM
- [IBM Rational DOORS Next Generation](#) (6.0.3) by [IBM](#)  
Scope: RM
- [in-STEP BLUE](#) (5.1.3) by [microTool GmbH](#)  
Scope: Project Management, RM, Testing
- [Innovator for Business Analysts](#) (13.1) by [MID GmbH](#)  
Scope: Visual Modeling, RM
- [inteGREAT](#) (v8.7.13) by [eDev Technologies](#)  
Scope: RM, RD, Visual Modeling
- [Integrity Lifecycle Manger \(was PTC Integrity\)](#) (10.9) by [PTC Integrity](#)  
Scope: RM, Testing
- [Jama](#) (8.8) by [Jama Software](#)  
Scope: RM, Testing
- [JIRA Software](#) (7.2.4) by [Atlassian](#)  
Scope: Issue Management, Agile, Project Management, RM
- [Kovair ALM Studio](#) (8.5) by [Kovair Software, Inc.](#)  
Scope: RM, Testing
- [Mingle](#) (16.2) by [Thoughtworks](#)  
Scope: RM, Agile, Project Management
- [objectiF RPM \(was in-STEP RED\)](#) (3.2) by [microTool GmbH](#)  
Scope: Project Management, RM, agile
- [Polarion Requirements](#) (2016 SR2 (Build 3.10)) by [Siemens](#)  
Scope: RM
- [Serena Dimensions RM](#) (12.3) by [Serena Software](#)  
Scope: RM
- [TestTrack RM](#) (2016.0.2) by [Seapine Software, Inc.](#)  
Scope: RM
- [TopTeam Analyst](#) (7.3) by [TechnoSolutions](#)  
Scope: Visual Modeling, RM
- [VersionOne](#) (16.3.2.207) by [VersionOne](#)  
Scope: RM, Agile
- [Visure Requirements](#) (4.8) by [Visure](#)  
Scope: RD, RM



## Customer Engagement vs. Involvement





## Customer Engagement vs. Involvement





## Customer Engagement vs. Involvement



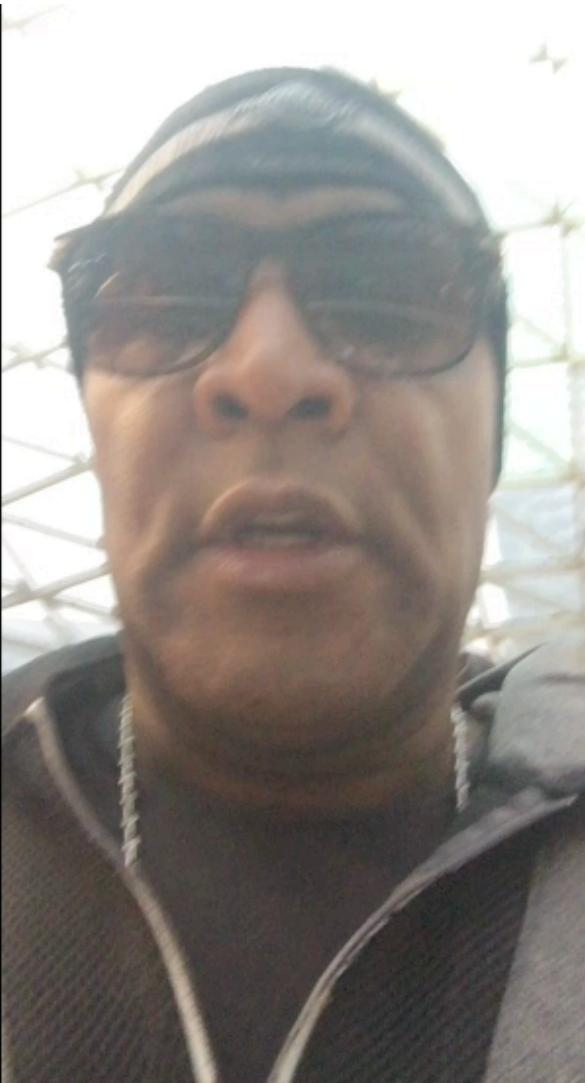


# Customer Engagement vs. Involvement





# Customer Engagement vs. Involvement





## Customer Involvement Example

The Customer Involvement Example dealt with me placing an order and waiting for the development team to deliver my order.



I placed the order, and had to wait to see if the order was correct.



## Customer Engagement Example

The Customer Engagement

Example dealt with me working [directly] with the development team in making my order.



I participated in every step of the order making process, and thus ensured that my order was correct.



# Customer Engagement Example





## Q&A Session

**ANY  
QUESTIONS?**