Traceability through the SDLC

Gilbert Regan, Supervised by: Dr Fergal Mc Caffery

1 Introduction

Irish Medtech in numbers (as of 2011)	
250	The number of Medtech companies in Ireland
50%	The percentage of indigenous Irish Medtech companies
€7.2 b	The value of annual Irish Medtech exports
25,000	The number of people employed in the industry

» Ireland's medical technology sector is evolving into one of the leading global clusters for medical devices and has been identified by the Iris Government as one of the key drivers of industrial growth for the future.

» Good traceability information is important to process improvement. It is fundamental for change impact analysis, requirements validation and regression testing among others. Additionally traceability is used to assure that safety related requirements are created from risk analysis activities.

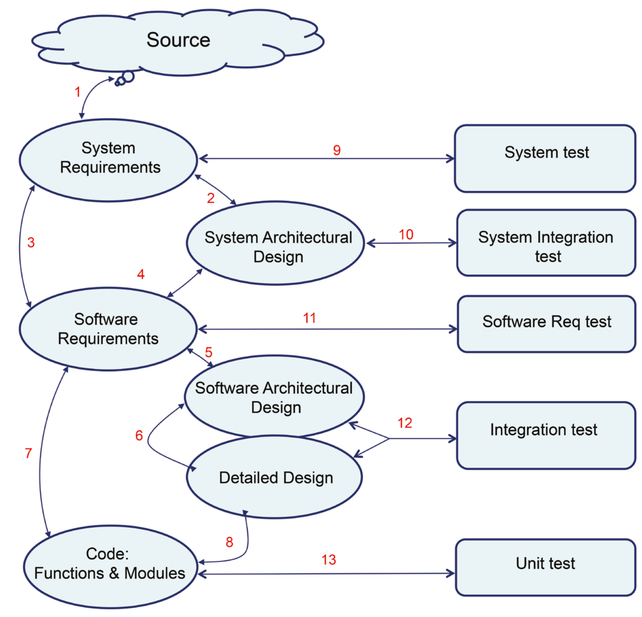
» Traceability is central to medical device software development and

» essential for regulatory approval. Due to the difficulties in implementing traceability (cost and complexity), many medical device companies are employing inefficient traceability processes.

Project Aim

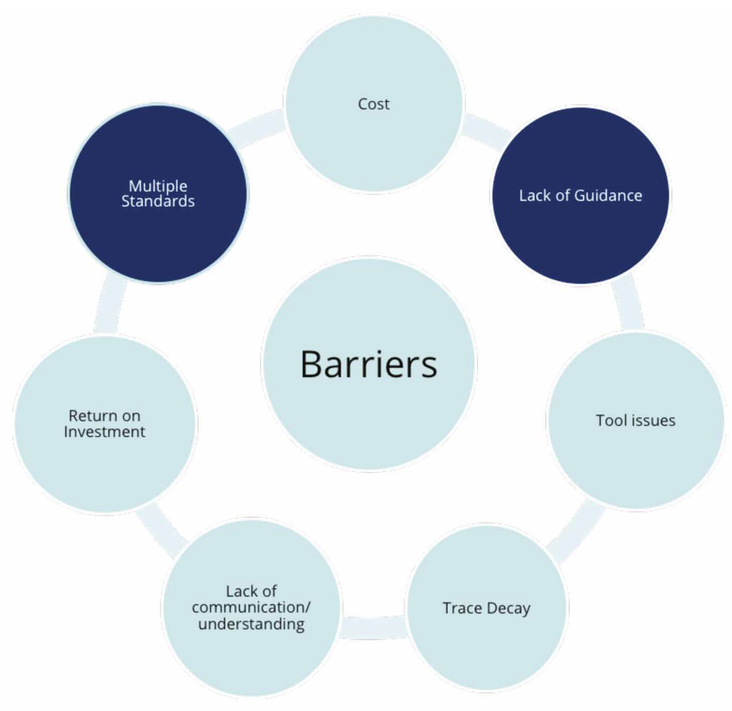
To assist medical device organisations improve their implementation of traceability and thus the quality of their software and put them on the road to regulatory compliance.

2 Requirements for Traceability



Link	Document
1,2,4,9,10	ISO 13485:2003 Medical Devices – Quality management systems – Requirements for regulatory purposes
3,6,11	IEC 62304:2006 Medical Device Software Lifecycle Processes
5,812,13	FDA:2002 General Principles of Software Validation
7	FDA:2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

3 Barriers and Proposed Solutions



Lack of Guidance/ Multiple Standards – Traceability Assessment Model and Traceability Roadmap

» Traceability Assessment Model based on 15504 Process Assessment Model

» Traceability Roadmap developed by:

1. Identify traceability requirements (or goals) from medical device standards
2. Logically group all goals into milestones
3. Order milestones based on 2 above
4. Validate generated roadmaps
5. Identify activities that can meet the identified goals
6. Validate activities in host organisations

4 Conclusions

» Software failure in the medical device domain can lead to injury or death. Controlling this risk is fundamental to producing quality software. To produce quality software, an effective requirements and hazards traceability process is required. Hence traceability is central to medical device software development. It is also an essential requirement for regulatory approval.

» There are many barriers to an organisation implementing traceability, and therefore most existing software systems do not employ traceability. However this is not an option within the safety critical domain

» This work has lead to the development of a traceability assessment model and traceability roadmap that mitigates the barriers of a) lack of guidance and b) multiple standards requirements for traceability

Publications

Regan et al., Traceability – Why do it? presented at SPICE 2012, Madrid, Spain
Regan et al., Impact of Standards on the Role and Application of Traceability in the Medical Device Domain presented at EuroSPI 2012, Vienna, Austria
Regan et al., The Barriers to Traceability and their Potential Solutions: Towards a Reference Framework presented at SEAA 2012, Cesme,Turkey
Regan, G., Mc Caffery, F., McDaid, K., Flood, D. (2013) Investigation of Traceability within a Medical Device Organization. In: International SPICE Conference Process Improvement and Capability dEtermination/ Bremen, Germany
Regan, G., Mc Caffery, F., McDaid, K., Flood, D. (2013) Implementation of Traceability Best Practices within the Medical Device Domain. In:European Systems and Software Process Improvement and Innovation Conference, EuroSPI/ Dundalk, Ireland
Regan, G., Mc Caffery, F., McDaid, K., Flood, D. (2013) Medical Device Standards' Requirements for Traceability during the Software Development Lifecycle and Implementation of a Traceability Assessment Model. In: Journal of Computer Standards & Interfaces DOI: 10.1016/j.csi.2013.07.012

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