# From justification requirements elicitation to their continuous production

Application in a medical technology company

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# Our context

# **Critical domains**





Hardware Software System

Traceability

Feasibility Architecture

Development

Pain

V&V

### Human expertises

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Neurostimulator

# Challenge : Confidence in justification



# Some vocabulary

**Justification requirement** : a proof element that must be reached to be compliant with a law. It cans be set through a standard or a guide

**Elicitation** : action to help experts to formalize their knowledge to keep and share them

Justification : an argumentation attesting that a justification requirement is fulfill

**Justification artefact** : a data (e.g. document, result) to establish in order to construct a justification

Improve confidence in justification management from requirement to production

# Justification Diagrams<sup>1</sup>

Derived from Toulmin argumentation schema<sup>2</sup>

Compliant with Goal-Structuring Notation (GSN)

Comprehensive notation to explain why a result is trustable

Captures the rationale logical structure of all evidence that leads to the acceptance of a high-level property

Only a notation but proved to be useful <sup>3 4</sup>

 $\Rightarrow$  A good starting point but need to be extended



1. Polacsek, T.: Validation, accreditation or certification: a new kind of diagram to provide Confidence

2. Toulmin, S.E.: The Uses of Argument

3. Duffau, C., Camillieri, C., Blay-Fornarino, M.: Improving confidence in experimental systems through automated construction of argumentation diagrams

4. Polacsek, T., S. Sharma, C. Cuiller et V. Tuloup. «The need of diagrams based on toulmin schema application : an aeronautical case study», EURO Journal on Decision Processes

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# Justification Pattern Diagram (JPD)



- Give an overview of the all justification requirements
- Elicitate links between justifications requirements

⇒ A way to structure justification requirements from standards to internal practices

(Rationale) Usage domain



# Justification Diagram (JD)



# JPD and JD



# A semantics for JPD and JD

#### Définition 5.1.1 : Relation de conformité

Soit  $\mathcal{A}$  l'ensemble des assertions,  $\mathcal{R}$  est une relation de conformité ssi  $\forall a_1, a_2, a_3 \in \mathcal{A}$ :

- $-a_1 \Re a_1$
- if  $a_1 \mathscr{R} a_2$  and  $a_2 \mathscr{R} a_1$  then  $a_1 = a_2$
- if  $a_1 \mathscr{R} a_2$  and  $a_2 \mathscr{R} a_3$  then  $a_1 \mathscr{R} a_3$
- $a_1 \Re a_2$  se lira  $a_1$  est conforme à  $a_2$ .



DUFFAU , C., T. POLACSEK M. BLAY -FORNARINO . 2018, Une sémantique pour les patrons de justification, INFormatique des ORganisations et Systèmes d'Information et de Décision 2018 (INFORSID)

# A Meta-model for JD



DUFFAU , C., T. POLACSEK M. BLAY -FORNARINO . 2018, Une sémantique pour les patrons de justification, INFormatique des ORganisations et Systèmes d'Information et de Décision 2018 (INFORSID)

# **Research conclusion**



Distinction between justification requirements and justification production



A semantics to formalize the approach



A meta-model to go to tools

⇒ Usefulness of JPDs and JDs

JPD and JD in action: application in the medical technologies company



• SME - a dozen of people

• Strong legacy - first french cochlear implant

• Focus on advanced R&D

• Agile development from hardware to software



### **Stakeholders:**

1 researcher/practitioner, 2 quality system managers, 3 technical leaders

Study guideline for a stage:

1.	The researcher designs a JPD according to quality management team and technical				
	leac	ler requirements			
2.	The	technical leaders			
	а.	Identify justifications items that must be produced			
	b.	Develop tools to produce them	JPD		
3.	Duri	ng the development step, the technical leaders			
	а.	Possibly define new activities			
	b.	Produce the necessary justifications	JD		
4.	During the deployment step, the quality managers and the researcher analyze the				
	diffe	erences between the original JPD and the JDs			
			JPU/JU revision		

5. During the audit, JPD and JDs are one of the supports of discussion with the authority

DUFFAU , C., T. POLACSEK M. BLAY -FORNARINO . 2018, Support of justification elicitation: Two industrial reports, Advanced Information Systems Engineering - 30th International Conference, CAiSE 2018

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# Prototyping



# Moving to development



Problem : For the company, good starting point but yet another way to abstract Real industry need : Use JPD and JD as a way to automate production and verification of justifications

# Industrial needs

Automate the production of justifications from justification requirements and artefacts in existing tools

Help the verification and validation of justifications regarding requirements

A seamless approach from the point of view of the quality management department





- Open source project management software
  - Roadmap
  - Issues
  - Documentation

- Used as Quality Management System (QMS)
  - $\circ$   $\;$  Justifications from specifications to product V&V  $\;$
  - The main software during audit





- Continuous Integration platform
  - Integrate code all together on a daily basis
  - Automate compilation, unit tests, integration tests, deployment, ...

algol
1 Au repos
altik
1 Au repos

- Daily at AXONIC
  - 5 tangled projects
    - Desktop software
    - Embedded software
    - Internal software
  - $\circ$  6 compilation and unit tests x5
  - 6 integration tests x8
  - 2 quality analysis x1



# **Justification Factory**

• Internal software developed during my PhD

- Management justification from the requirements to the production
  - Design JPD
  - (Automate) construction of JD
  - (Automate) verification and validation conformance

• Expose justification seamless services and justification services

# **Justification Factory**



# Going further with Jenkins



DUFFAU, C., B. GRABIEC M. BLAY-FORNARINO . 2017, Towards embedded system agile development challenging verification, validation and accreditation: Application in a healthcare company, ISSRE 2017-IEEE International Symposium on Software Reliability Engineering

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# Justification Factory with Jenkins



DUFFAU, C., B. GRABIEC M. BLAY-FORNARINO . 2017, Towards embedded system agile development challenging verification, validation and accreditation: Application in a healthcare company, ISSRE 2017-IEEE International Symposium on Software Reliability Engineering

# JPD for system validation



# About the usefulness in **Axonic**

Artefacte de justifications	Automatisation avant	Automatisation après	
Artelacts de Justifications	Justification Factory	Justification Factory	
Tests unitaires	OUI	OUI	
(~2000)	(mais seulement les artefacts)	001	
Tests d'intégration	OUI	OUI	
(~100)	(mais seulement les artefacts)	001	
Tests systèmes	NON	OUI	
(~50)	NON		
Tests exploratoires	NON	NON	
(~10)	NON	NON	
Sanity check	NON	NON	
(13)	NON	NON	
Traçabilité livraison	NON	OUI	
(6)	NON	001	

# Scale up : JPD for design dossier

• Under industrial properties

- JPD tracing all the justifications for ISO 13485 for AXONIC including
  - ISO 14971 Risks management
  - IEC 62304 Software in medical devices
  - IEC 62366 Usability engineering
  - IEC 60601 Safety and performance of medical electrical equipment

- Some metrics to give a hint
  - 184 documents on Redmine used as justification artefacts
  - 300 evidences
  - 175 conclusions

# Axonic justification -



#### NEUROSTIMULATION SYSTEMS

Codification	_ST_0005_B
Edition	В
Nom du projet	
Référence du projet	022_
Diffusion	AXONIC

#### Historique

Edition	Date	Motifs	Auteur
A	24/07/2017	Création	BG
В	21/11/2017	Modification	BG

#### Modification

- Edition B :
  - Modifications suite aux modification dans \_\_\_\_\_ST\_0001
  - 0

(#7373)

#### Objet

Le présent document décrit

#### Références

ST\_0001\_B : Spécifications techniques (ticket principal #7217)

#### Approbation du document

Auteur : BG	Vérificateur : LW	Vérificateur : FS
Date : 21/11/2017	Date : 23/11/2017	Date: 27/11/2017
Acceptation numérique : OK BG	Acceptation numérique : OK LW	Acceptation numérique :OK FS

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# Master file for design dossier REDMINE flexible project management



Phase projet	Туре	Reference	Intitule	Lien	Date	Auteur	Approuve?	Verrouille?
INITIALISATION								
Initialisation	RIN	_RIN_0001_A	Revue d'initialisation	RIN	14/06/17	LG	OUI	OUI 26/06/17 rev.3
Initialisation	RIN	_RIN_0001_B	Revue d'initialisation	_RIN_0001_B	27/10/17	LG	OUI	OUI 30/10/17 rev.6
Initialisation	RIN	_RIN_0001_C	Revue d'initialisation	_RIN_0001_C	27/11/17	LG	OUI	OUI 05/12/17 rev.6
Initialisation	RIN	_RIN_0001_D	Revue d'initialisation	_RIN_0001_D	22/02/18	LG	OUI	OUI 19/03/18 rev.8
DONNÉES ENTRÉE								
Données d'entrée	EE	EE_001_A	Exigences essentielles	EE_001_A	04/07/17	LG	OUI	OUI 18/07/17 rev.16
Données d'entrée	EE	EE_001_B	Exigences essentielles	EE_001_B	27/07/17	LG	OUI	OUI 31/07/17 rev.4
Données d'entrée	EE	EE_001_C	Exigences essentielles	EE_001_C	27/03/18	JP	OUI	21/05/18 rev.62
Données d'entrée	DE	DE_001_A	Données d'entrée de	_DE_001_A	26/06/17	LG	OUI	OUI 07/07/17 rev.14
Données d'entrée	DE	DE_001_B	Données d'entrée de	DE_001_B	11/07/17	LG	OUI	OUI 24/07/17 rev.26
Données d'entrée	DE	DE_001_C	Données d'entrée de	DE_001_C	11/08/17	LG	OUI	OUI 11/09/17 rev.10
Données d'entrée	DE	DE_001_D	Données d'entrée de	DE_001_D	21/02/18	LG	OUI	OUI 21/03/18 rev.11

# Justification Factory with Redmine



# About the usefulness in Axonic

		Avant Justification Factory	Après Justification Factory
Nombre total de documen	358	377	
Nombre de documents de (présence d'une section "A	165	184	
	pas d'auteur	15	8
Nombros do documento	pas signé par l'auteur	4	5
de justification en erreur	signé par l'auteur, mais non approuvé	11	5
3	pas de date de signature	4	2
	approuvé, mais non verrouillé	22	10
Taux d'erreur dans les doc	33.9	16.3	
Nombre de documents de	159	184	
Nombre de documents de oubliés dans le MasterFile	9	0	
Nombre de documents de présents dans le MasterFil	13	0	
Taux d'erreur dans le Mast	13.8	0.0	

# Industrial needs

Automate the production of justifications from justification requirements and artefacts in existing tools

Help the verification and validation of justifications regarding requirements

A seamless approach from the point of view of the quality management department

# **Conclusion and perspectives**

### Usefulness of JPDs and JDs

- → Distinction between justification requirements and justification production
- → Formally defined



### Fill industrial needs

- → Automate production and V&V for justifications
- → Positive feedbacks from industrials



Application to none-critical domains

→ ROCKFlows : Meta-learning to predict the best workflow

# Provide integration of dedicated tools with others common industrial technologies

- → Requirements and documentation : Atlassian
- → Code : SonarQube

## **Questions, Comments ?**

## **AXONIC** feedbacks

### **Medical technologies**

### • Tangled standard requirements

- IEC 62304 Medical device software
- IEC 62366 Application of usability eng. to medical devices
- ISO 14971 Medical devices risk management

### ⇒ Redundant justifications → JPDs help to identify them

- Agile development
  - 2-weeks sprints
  - Continuous Integration

## ⇒ Justification tsunami → JDs capture the incrementality

- SME
- ⇒ Justification is handle by everyone and need to be efficient
- → JPD ← → JD helps to automate production



# Standard evolution in JPD



# Standard evolution in JD



# Requirement Eng. - i\*

Early-phase requirements

Focus on who and what (process oriented)

In version 2.0, replace soft-goal by quality<sup>1</sup>

Extension to put argumentation on it but not to justify<sup>2</sup>

### ⇒ They are a way to identify what we need to justify but not how

1. Dalpiaz, F., Franch, X., Horkoff, J.: istar 2.0 language guide

2. Van Zee, M., Marosin, D., Bex, F., Ghanavati, S.: Rationalgrl: A framework for rationalizing goal models using argument diagrams.



# Assurance Case - SACM

Historically Goal Structuring Notation<sup>1</sup> (GSN) and Claim-Argument-Evidence<sup>2</sup> (CAE)

Used for safety case

New OMG standard : Structured Assurance Case Metamodel <sup>3</sup>

Focus on 3 aspects :

- Argumentation
- Artifact
- Assurance Case

### ⇒ A pivot conceptual model not aiming to manage justifications

1. Kelly, T., Weaver, R.: The goal structuring notation /- a safety argument notation

2. Emmet, L., Cleland, G.: Graphical notations, narratives and persuasion: a pliant systems approach to hypertext tool design

3. OMG: Structured assurance case meta-model (sacm)



# I\* and JPD



# Aircraft manufacturing case study

### **Stakeholders:**

1 researcher, aircraft architects, workload experts

### **Study guideline:**

1. The researcher goes 2 days in the product line

2. The researcher, aircraft architects, workload experts iteratively design JDs for each main project stage based on past projects

3. The stakeholders abstract the JDs to capture global practices into JPDs

JPD

# During preliminary design



# During advanced design



# Early development



# **Justification Diagrams lifecycle**

