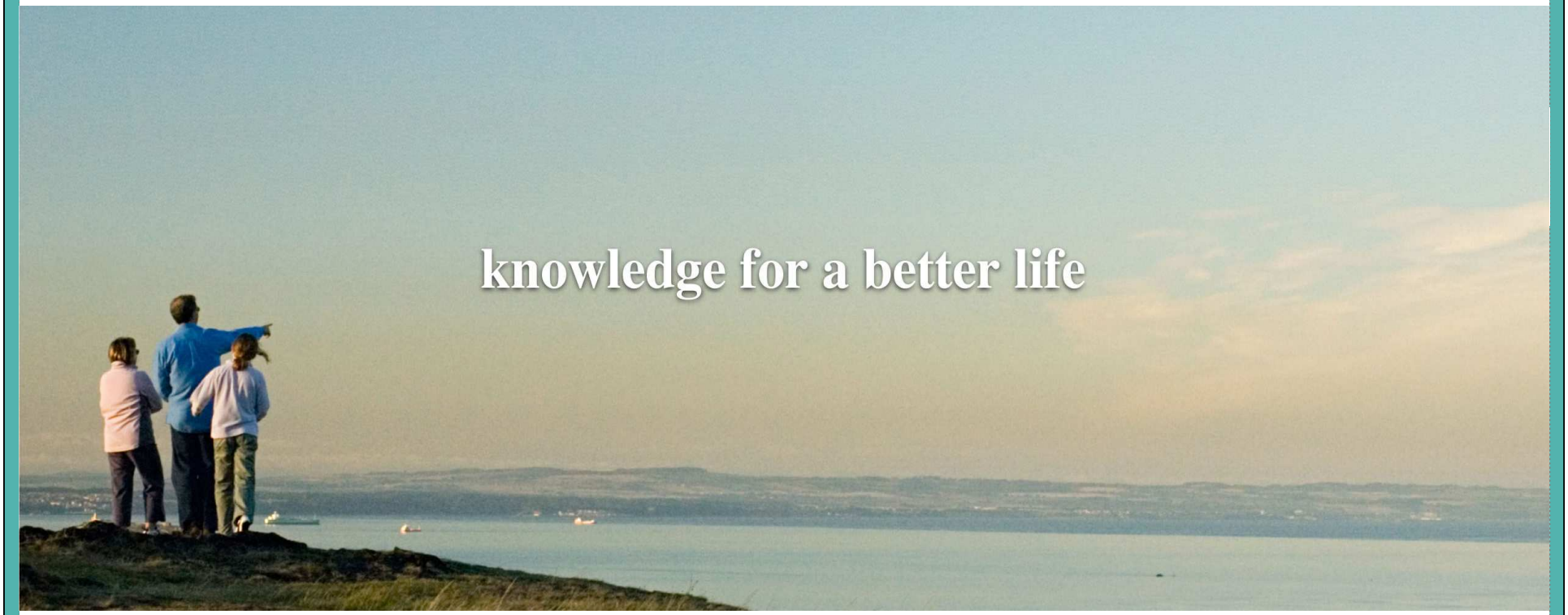

Risk assessment approach to data integrity

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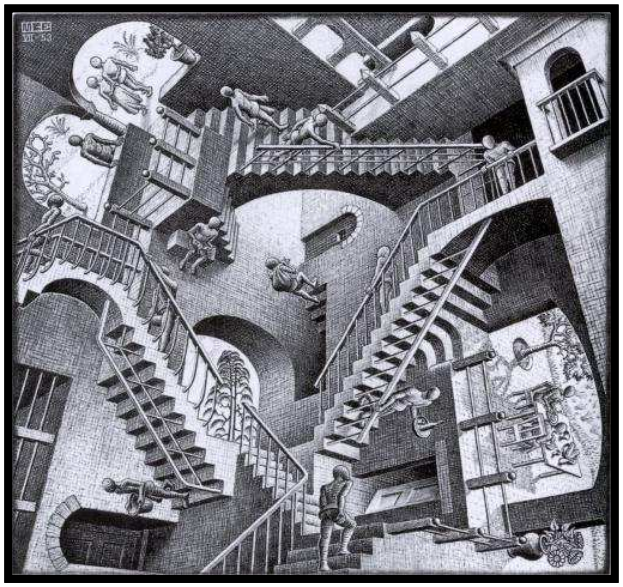
Donato Migliarino

November 10, 2017

Introduction



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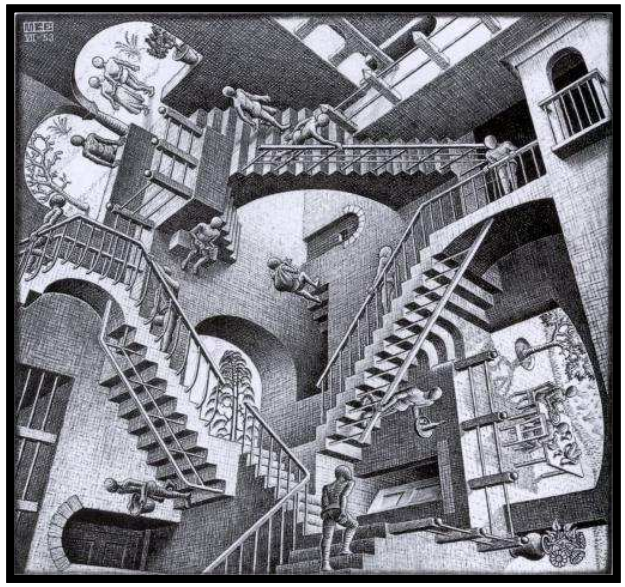
Multiple business processes

Many activities per business process

Lots of data

Companies shall map all the business processes and value them from the data integrity point of view, and understand the number of activities that have to comply with the regulation.

Introduction



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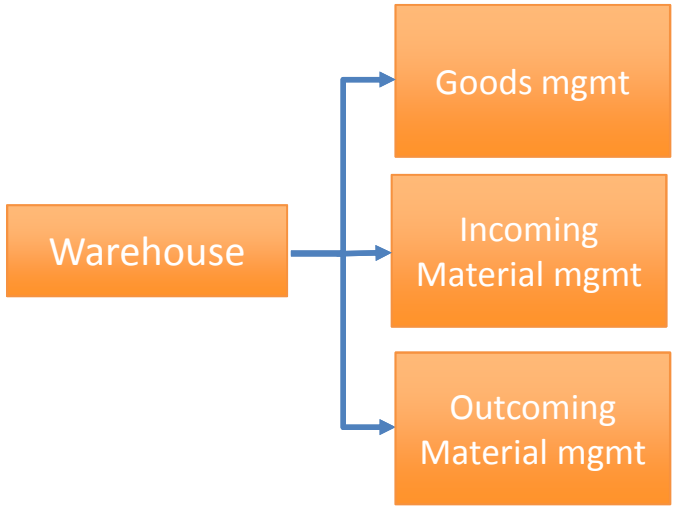
Business process mapping

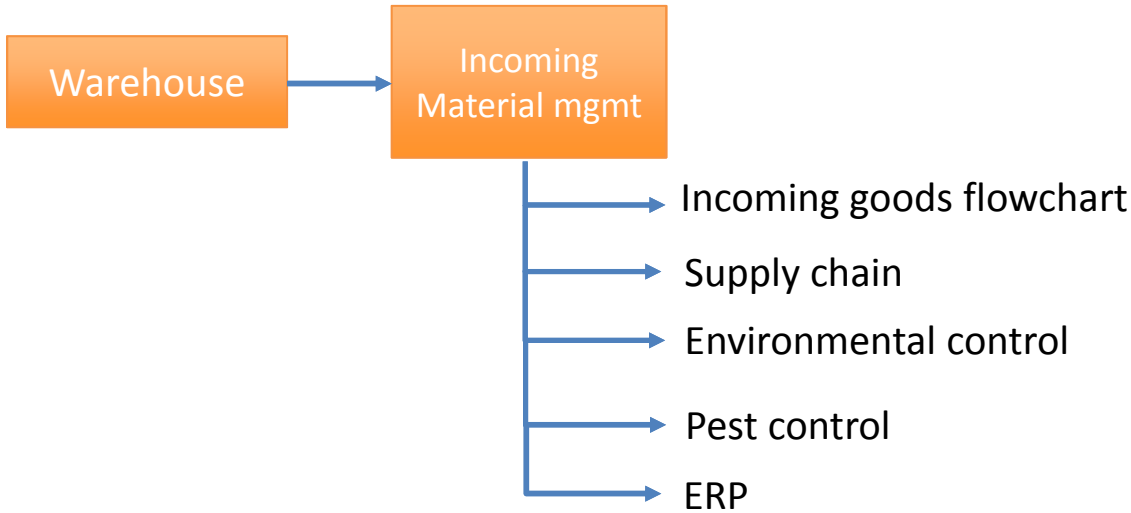
Business process: A business process is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal). They are measurable and monitorable over time by using key performance indicators.



Business process mapping

Business process: A business process is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal). They are measurable and monitorable over time by using key performance indicators.

Activity: is a part of a process, and therefore it is not useful to decompose further.



Scope of the risk assessment

Value the quality and integrity of the data produced by business processes

Classification of business activities, assigning them a risk of data integrity failure, and define the quality strenght to solve the deficiencies.

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Risk

The risk is the **company data adulteration**.

Model: Failure Mode and Effect Analysis (FMEA)

Risk

The higher the value, the greater the risk for data integrity failure, the earlier CAPA activies shall be implemented.

LOW	Actions identified in the GAP Analysis can have a long term implementation
MEDIUM	Actions identified in the GAP Analysis shall be implemented within a year (within 12 months max.).
HIGH	Company shall implement an immediate CAPA, in order to reduce the risk to a lower level and increase the level of security of data.

Risk Analysis

Severity, **Probability** and **Detectability**

Severity

Depends on:

- Type of data;
- Data impact on processes and products;

Severity

Type of data

- Specifications (Raw material, semi-finished, finished product)
- Analytical methods
- Certificates of Analysis
- Master Batch Record and Executed Batch Record
- Policy and procedures
- Qualification protocols
- Batch release
- Training
- Complaints and recalls
- PQR

Severity

Type of data

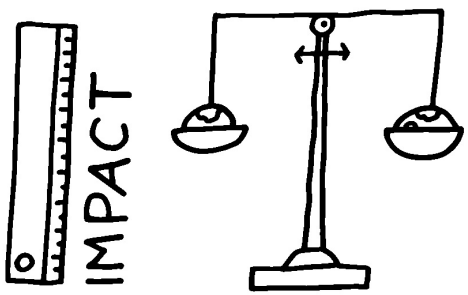
The higher the importance of the data managed, the higher the impact of data loss and adulteration can have on quality of the product / patients' health and company's reputation.

Severity

<u>Impact of the data</u> *(the butterly effect)*

Data produced at the beginning of the process could have more impact of data produced at the end.

Data produced in an isolated process have less impact of data produced in a multistep process (in case of adulterated or damaged data).



Severity

How to evaluate Severity? Try answering these questions!

SEVERITY	Is the data produced by a GMP activity?
	Is the data used for batch release?
	Is the data produced at the beginning of the business process?
	Is the data produced in a multistep process?

No. of positive answers	Risk Number
0	1
1 - 2	5
3 – 4	9

Probability

It is the probability to produce adulterated data and/or to generate data by-passing authorization step or outside SOPs.

Depends on:

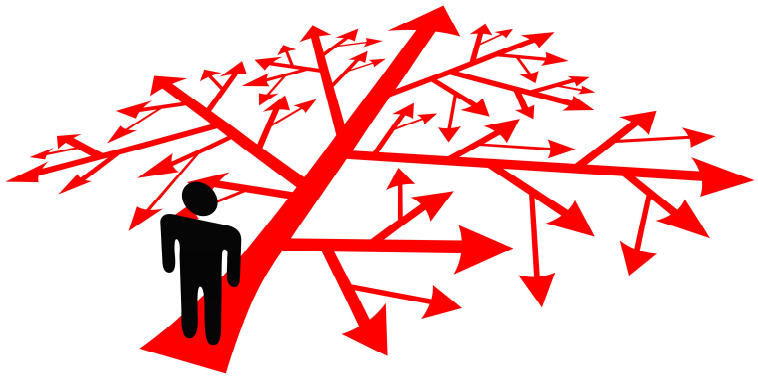
- Complexity and precision of the process;
- Automation / human interface;
- Training and segregation of duties.

Probability

Complexity and precision of the process

The complexity of the process is the number of data produced by the activity/ies and that should be reviewed. The higher the complexity, the greater the number of data produced, the lower the probability of adulterated data identification.

The precision of the activity means the possibility of interpretation of a data or a document (i.e. form). The higher the possibility of interpretation, the greater the risk of data integrity failure.



Probability

Automation / human interface

Computerized systems, even validated ones, are weak from a data integrity point of view if the imput is human-based → there is a possibility of interpretation of the data to be recorded.

Probability

Training and segregation of duties

Lack of training and segregation of duties increase the risk of data integrity failure.

Probability

How to evaluate Probability? Try answering these questions!

PROBABILITY	Is the business process complex (multistep process with a lot of activities and data produced)?
	Are there forms to be filled out by the personnel or is there the possibility to interpret the data managed by the company system?
	Is the personnel untrained for the activity?
	Is the activity manually handled or human interfaced?

No. of positive answers	Risk Number
0	1
1 – 2	5
3 - 4	9

Detectability

How to evaluate Detectability? Try answering these questions!

DETECTABILITY	Is there a review of the data produced by the activity (double check or electronic review)?
	Is the activity periodically audited (self inspection / periodic review on activity)?
	Is the activity periodically tested (challange test) for data integrity?
	Is the activity completely validated ‘’for the intended use’’?

No. of positive answers	Risk Number
3 - 4	1
1 - 2	5
0	9

Risk Priority Number (RPN)

Risk Priority Number is the product between Severity (S), Probability (P) and Detectability (D).

$$RPN = S \times P$$

		Severity		
		1	5	9
Probability	1	1	5	9
	5	5	25	45
	9	9	45	81

Low	Medium	High
1 – 9	25 – 45	81

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Risk Priority Number (RPN)

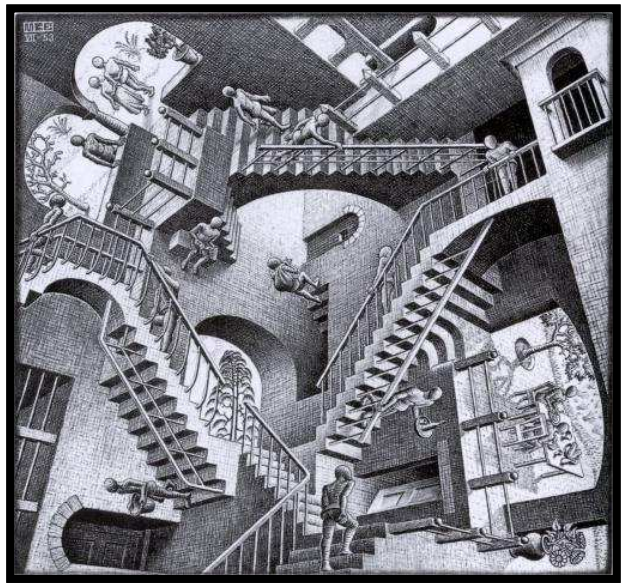
Risk Priority Number is the product between Severity (S), Probability (P) and Detectability (D).

$$RPN = S \times P \times D$$

		1	5	9
Low	1	1	5	9
	9	9	45	81
Medium	25	25	125	225
	45	45	225	405
High	81	81	405	729

Low	Medium	High
1 – 81	81 – 405	729

Result



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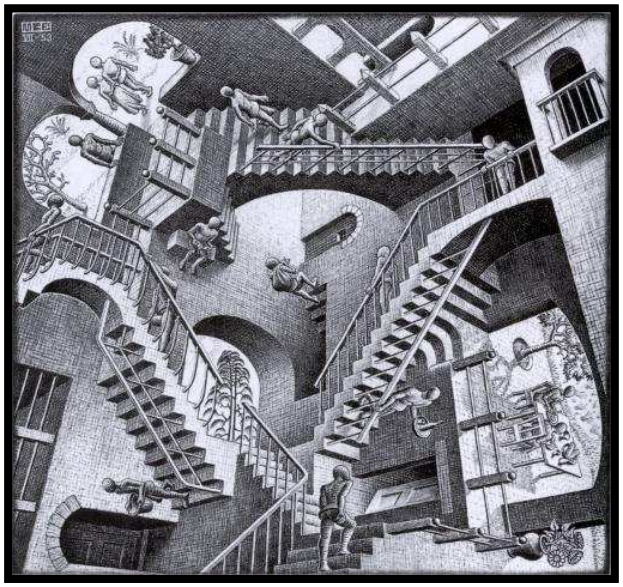
Result



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Quality Control

Produzione

Quality Assurance

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Example of risk analysis

Dept	Business Process	Activity	SOPs	S	P	D	RPN	Note
QC	Finished product Analysis	Approval of FP	PQC-XX	9	5	5	225	
QC	Raw Material Analysis	Approval of raw material	PQC-XX	5	1	1	5	
QA	Batch Release	Batch Record review	PQA-XX	5	5	5	125	
QA	Batch Release	Batch Release	PQA-XX	5	1	1	5	
MG	Incoming Material	Pest control mgmt.	PMG-XX	1	5	5	25	
MG	Incoming Material	Incoming material mgmt.	PMG-XX	5	5	1	25	
PR	Production	Validation of equipment	PPR-XX	5	5	5	125	
PR	Production	Batch record execution	PPR-XX	5	5	1	25	

Example of risk analysis

Dept	Business Process	Activity	SOPs	S	P	D	RPN	Note
QC	Finished product Analysis	Approval of FP	PQC-XX	9	5	5	225	Medium risk
QA	Batch Release	Batch Record review	PQA-XX	5	5	5	125	Medium risk
PR	Production	Validation of equipment	PPR-XX	5	5	5	125	Medium risk
MG	Incoming Material	Pest control mgmt.	PMG-XX	1	5	5	25	Low risk
MG	Incoming Material	Incoming material mgmt.	PMG-XX	5	5	1	25	Low risk
PR	Production	Batch record execution	PPR-XX	5	5	1	25	Low risk
QC	Raw Material Analysis	Approval of raw material	PQC-XX	5	1	1	5	Low risk
QA	Batch Release	Batch Release	PQA-XX	5	1	1	5	Low risk

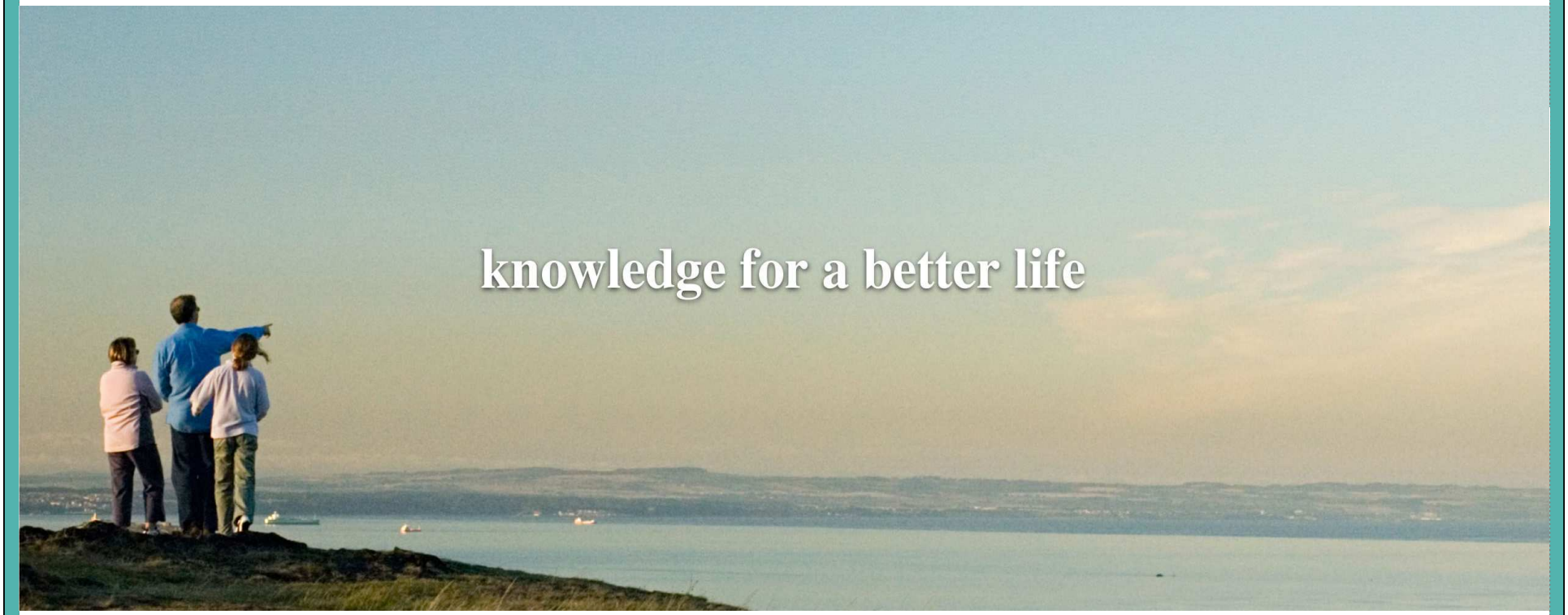
Risk analysis paradox

Severity: 9 → High risk data with an high impact on the processes

Probability: 9 → Complex and not clear paper based processes

Detectability: 9 → No control of the data produced

RPN = 729 → **Are you sure of the quality system of the process?**



THANKS FOR YOUR ATTENTION

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