Procedimento “Quantitativo” de Avaliação de Risco

GESTÃO DE RISCO CORPORATIVO

- Como deve ser feita e documentada uma avaliação de risco?

- Alguém já realizou?

GESTÃO DE RISCO CORPORATIVO

- Exigências de alguns mercados como EU e USA.

- Produto Médico para EU é exigido Análise de Risco para Registro do Produto, Seguindo ISO 19.471: 2007.
  - Análise de risco deverá ser atualizada após produção e comercialização.

GESTÃO DE RISCO CORPORATIVO “DE QUALIDADE”

1. SOP – Gerente de Qualidade prepara, emite e aprova um procedimento, lista os principais riscos de qualidade ou do negócio conhecidos.
2. Convoca uma reunião, revisa e ranqueia todos os riscos seguindo SOP.
3. Gerente de Qualidade apresenta resultado em reunião de Direção.

Como fazer? Exemplo?

- Probabilidade (1-5)
- Severidade (1-5)
- *Probabilidade de Detecção (1-5)

*Nem todos utilizam este parâmetro. A maioria utiliza unicamente probabilidade e severidade.

Exemplo 1- Qualidade

		RATING				
		Probabilidade	**Severidade	Probabilidade de Detecção	Rísco =S*P*PD	Observações
Químico	Contaminação Microbiológica	3	5	5	75	SOP de C&S implementado lavagem com NaOH em jan 2012, add preservativo junho 2012
	Separação de Fórmula	1	3	3	9	
	Efeito Adverso Leve	2	2	4	16	Veja Histórico
	Efeito Adverso Grave	1	5	4	20	Veja Histórico
	pH for a do especificado	1	2	1	2	
	Mudança de Coloração do Produto	3	2	1	6	
Embalagem	Troca de Produto	1	2	1	2	
	Frasco Errado Cor	1	3	1	3	
	Rótulo Trocado	2	3	3	18	
	Texto Errado	1	5	2	10	
Regulatório	Ingestão	3	5	4	60	
	Contaminção por metal	1	3	1	3	
	Contaminção por Inseto	1	4	1	4	
	Contaminção por Cabelo	2	4	1	8	
	Mudança de Coloração do Produto	3	2	1	6	
	Falta Ingrediente no Rótulo	1	5	2	10	

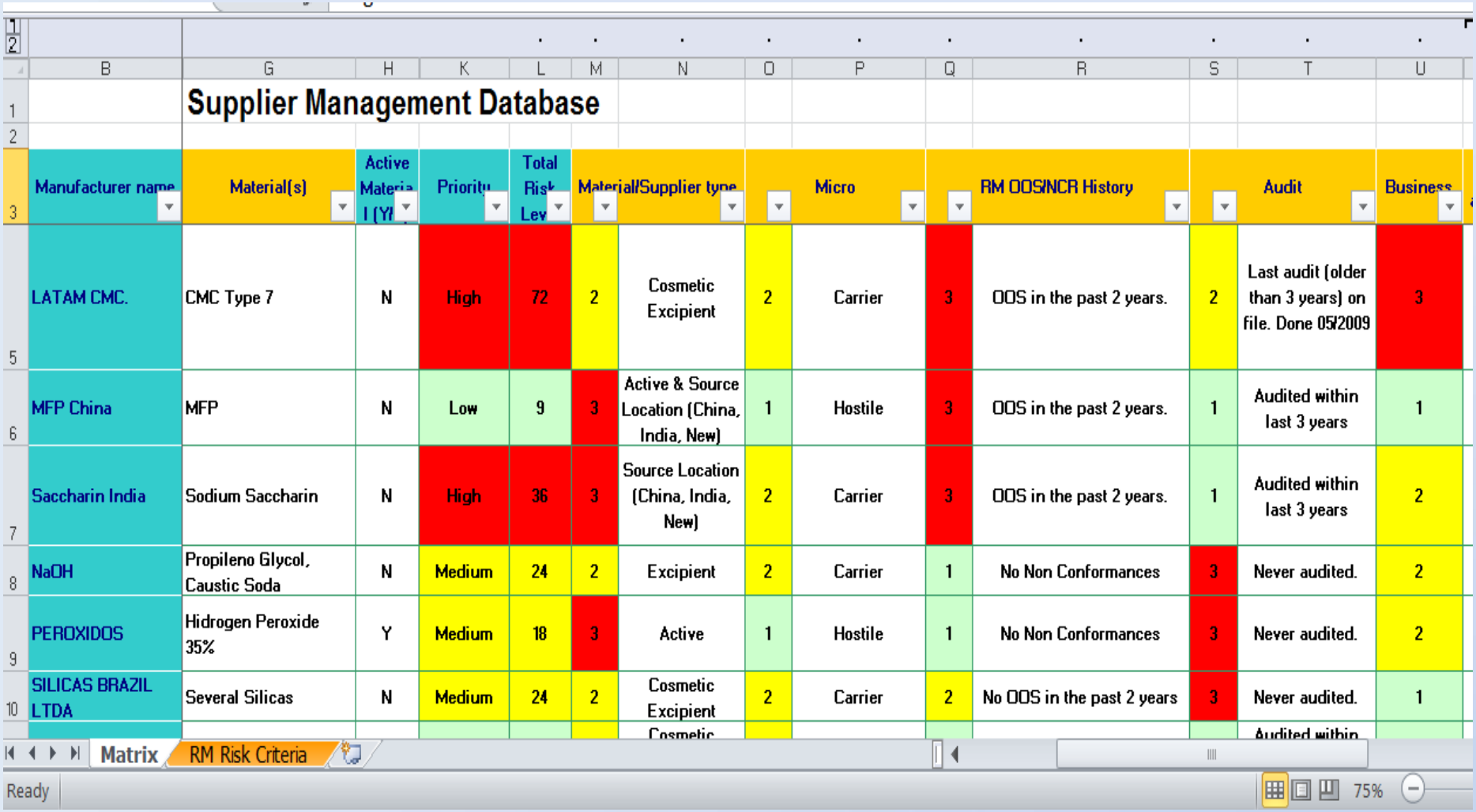
Alto	50 - 125
Médio	16 to 49
Baixo	1 to 15

Exemplo 2 – Fornecedor

	Material / Supplier Type	Micro	Data History	Audit	Business
Low - Level 1	Cosmetic Commodity Backup Supplier	Hostile	No Non Conformances	Audited within last 3 years No Severe ratings.	No supply disruption in the last year. Other sources of supply available. No business in the past year
Medium - Level 2	Excipient Personal Care Functional	Carrier	No OOS in the past 2 years	Last audit (older than 3 years) on file. No A ratings.	Single qualified source. Experienced regulatory threats in the last year. Experienced inbound logistics issues in the last year. Pricing pressure in the last year. Is the supplier's principal customer. Experienced an incident that caused a plant shutdown in the last year.
High - Level 3	Active Regulated Material (ie Glycerin - DEG requirements) New Material New Supplier Source Location Risk Significant Change	High Micro Risk Supportive Micro Contamination in past 2 years	No data OOS in the past 2 years.	Never audited. A Ratings in last Audit Last audit older than 5 years on file.	Supply Disruption in the last year. Supplier is Unique Material exclusively made Country of manufacturing critical economical/political situation in the last year.

27-243	High
16 to 26	Medium
1 to 15	Low

Fornecedores



Supplier Management Database

Manufacturer name	Material(s)	Active Materia l (Yl	Priority	Total Risk Lev	Material/Supplier type	Micro	RM OOS/NCR History	Audit	Business
LATAM CMC.	CMC Type 7	N	High	72	2	Cosmetic Excipient	2	Carrier	3	OOS in the past 2 years.	2	Last audit (older than 3 years) on file. Done 05/2009	3
MFP China	MFP	N	Low	9	3	Active & Source Location (China, India, New)	1	Hostile	3	OOS in the past 2 years.	1	Audited within last 3 years	1
Saccharin India	Sodium Saccharin	N	High	36	3	Source Location (China, India, New)	2	Carrier	3	OOS in the past 2 years.	1	Audited within last 3 years	2
NaOH	Propileno Glycol, Caustic Soda	N	Medium	24	2	Excipient	2	Carrier	1	No Non Conformances	3	Never audited.	2
PEROXIDOS	Hidrogen Peroxide 35%	Y	Medium	18	3	Active	1	Hostile	1	No Non Conformances	3	Never audited.	2
SILICAS BRAZIL LTDA	Several Silicas	N	Medium	24	2	Cosmetic Excipient	2	Carrier	2	No OOS in the past 2 years	3	Never audited.	1

Matrix | RM Risk Criteria

Ready 75%

Exercício

- Dividir a turma em 4 grupos
- Utilizando um dos 4 cenários apresentados
- Utilizando o modelo de análise de risco apresentado.

1. Simular uma análise de risco, identificando os 3/5 principais riscos
2. Rascunhar um organograma para empresa de alocação/concentração de recursos $$$ para controlar os riscos existentes.
3. Tempo 15 minutos
4. Apresentação do resultado 5 minutos/grupo.

Exemplo Europa – Produto Médico

INTERNATIONAL STANDARD ISO 14971:2007(E)

Medical devices — Application of risk management to medical devices

1 Scope

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.

This International Standard does not apply to clinical decision making.

This International Standard does not specify acceptable risk levels.

This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.

2 Terms and definitions

Exemplo Europa – Produto Médico

RISK ASSESSMENT AND CONTROL

(Product characteristics that could impact on safety)

Intended use/purpose/Element	Known or foreseeable hazards	Probability	Severity of harm	Risk evaluation	Risk acceptability	6.Planning of Risk control measures	Date of realization	Information results	Completeness of risk evaluation (Y/N)
						performed in Qualified System and Equipments. The Process is validated. The batch records are reviewed by Supervisor and Quality Assurance prior to release. Finished product key release specifications are evaluated prior to release.	May 2011	protocols and report Batch Record InBatch System Database SAP Warehouse Management System	
Color Change	Yellowish Aesthetic / Efficacy	3	2	6	Acceptable	Formulation was designed to avoid yellowish aspect. Raw material charge has double verification and documentation in batch record which is reviewed by Supervisor and Quality Assurance prior to release. Finished product aesthetic is evaluated prior to release. Color change does not impact on the safety of the product.	Dec 2010 May 2011	Technical bundle Book Batch Record & Inspection records	Y
Error in identity of raw material charged to batch	Safety/Efficacy	2	3	6	Acceptable	Identification labeling of raw material receipts is examined and each shipment of every material is tested for identity. SAP WMS System generates specific batch as well specific handling units per material per lot. The label on each container of raw materials charged to the batch is examined by two Operators prior to weighing and charging the material to the batch and it is recorded in InBatch System. This operation is documented in the batch record, which is reviewed by Supervisor and Quality prior to release. Finished product is tested against key release	Dec 2010 May 2011	Batch Record InBatch System Database SAP Warehouse Management System	Y

Exemplo Europa – Produto Médico

RISK ASSESSMENT AND CONTROL

(Product characteristics that could impact on safety)

Intended use/purpose/Element	Known or foreseeable hazards	Probability	Severity of harm	Risk evaluation	Risk acceptability	6.Planning of Risk control measures	Date of realization	Information results	Completeness of risk evaluation (Y/N)
Risk Management report									
						specifications prior to release.			
Error in raw material weights	Efficacy	2	3	6	Acceptable	Each product recipe is loaded in an InBatch System that is responsible to manage pre weight and addition. Dual weight verification and documentation in batch record which is reviewed by Supervisor and Quality prior to release. Finished product is tested against key release specifications prior to release.	Dec 2010 May 2011	Batch Record InBatch System Database	Y
Incorrect process (mixing times, raw material addition sequence)	Efficacy	1	3	3	Acceptable	Each product recipe is loaded in a InBatch System that is responsible for managing entire process (mixing times, raw material addition sequence) Documentation is reviewed by Supervisor and Quality Assurance prior to release. Finished product is tested against key release specifications prior to release.	Dec 2010 May 2011	Batch Record InBatch System Database	Y
Labeling mix-up	Safety	1	3	3	Acceptable	Labeling is checked when brought to production line. Operator checks the label during production. Physical standards are maintained in the lines to avoid mix-up. Batch record is reviewed by the Supervisor and by Quality Assurance prior to release.	Dec 2010 May 2011	Batch Record Quality Rate in the Line	Y
Microbiological Growth	Safety	2	3	6	Acceptable	Raw Materials are tested and released prior to product release. Equipment is designed according to Cleaning and Sanitization guidelines. C&S processes are validated. Finished product is tested	Dec 2010 May 2011	Inspection Results in SAP System. Validation reports Certificates of Analysis	Y

SOP – Produto Médico

PS/INF 1/2010

Quality Risk Management

Quality Risk Management

Implementation of ICH Q9 in the pharmaceutical field
an example of methodology from PIC/S

Document

> Authors:	L. Viornery (AFSSAPS)
	Ph. Le Goff (H&LG Consultants)
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Content

GESTÃO DE RISCO CORPORATIVO

- Plano de ação deve ser preparado com objetivo de reduzir os riscos de maior grau de severidade que podem ser reduzidos.
  - Ações
  - Responsáveis
  - Prazos
  - Resultado esperado

GESTÃO DE RISCO CORPORATIVO

- Resultado da Avaliação de Risco e Plano de Ação deve ser apresentada e aprovada pela Direção da Qualidade e/ou Alta Gerência.

- Deve ser periodicamente atualizada, anualmente ou trimestralmente em reuniões de alta gerência reportando progressos, incluindo novos riscos ou reduzindo severidade dos riscos que tiveram ações implementadas.

Obrigado