GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality

María Pellín Amorós

Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

Who are we?

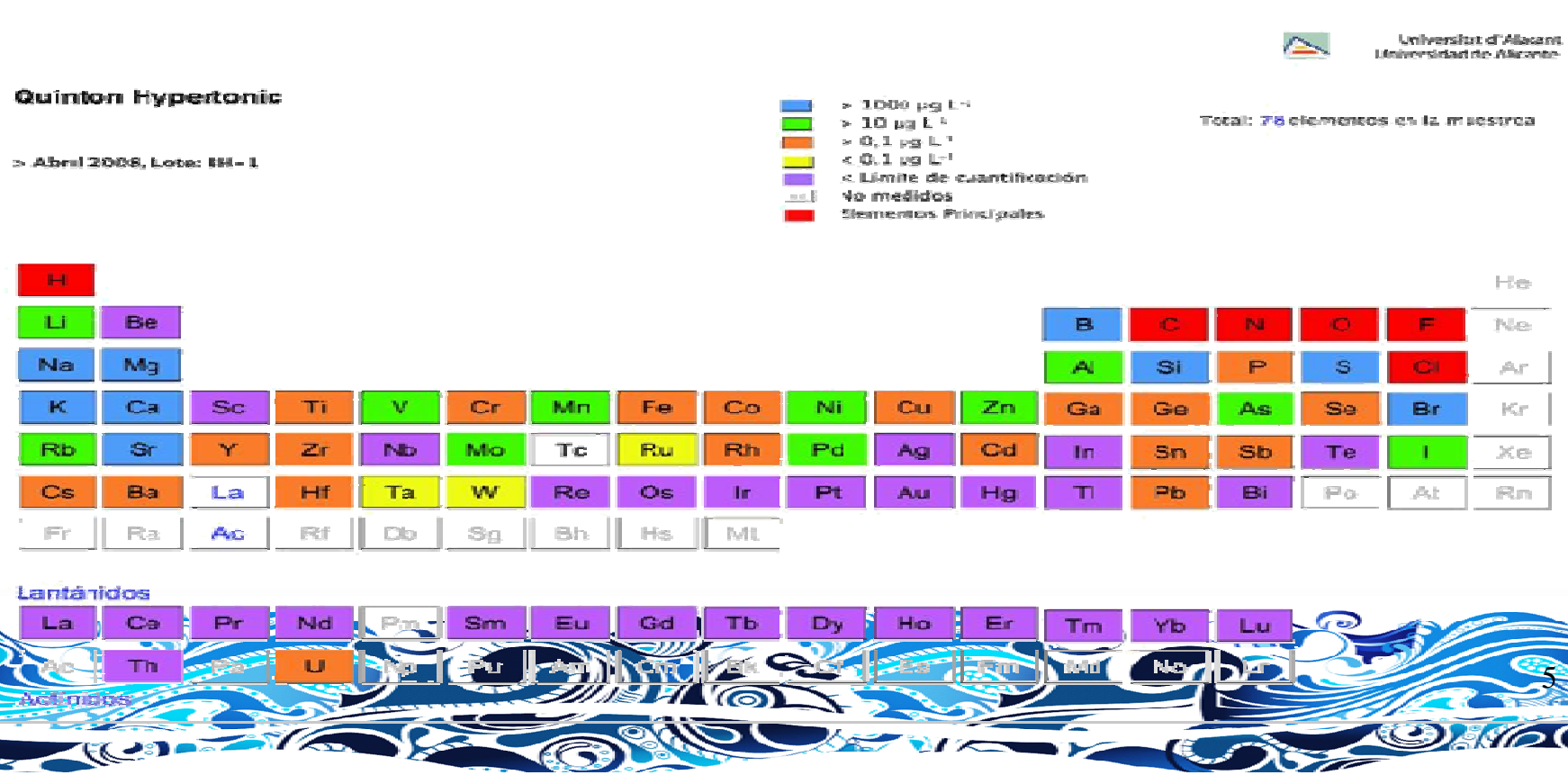
- Seawater products
  - –Dietary supplements
  - –Cosmetics
  - –Medical devices





Who are we?

- Rene Quinton, Biology and Physiology.
- 78 different elements in seawater.



Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

Advance Quinton Protocol







Advance Quinton Protocol

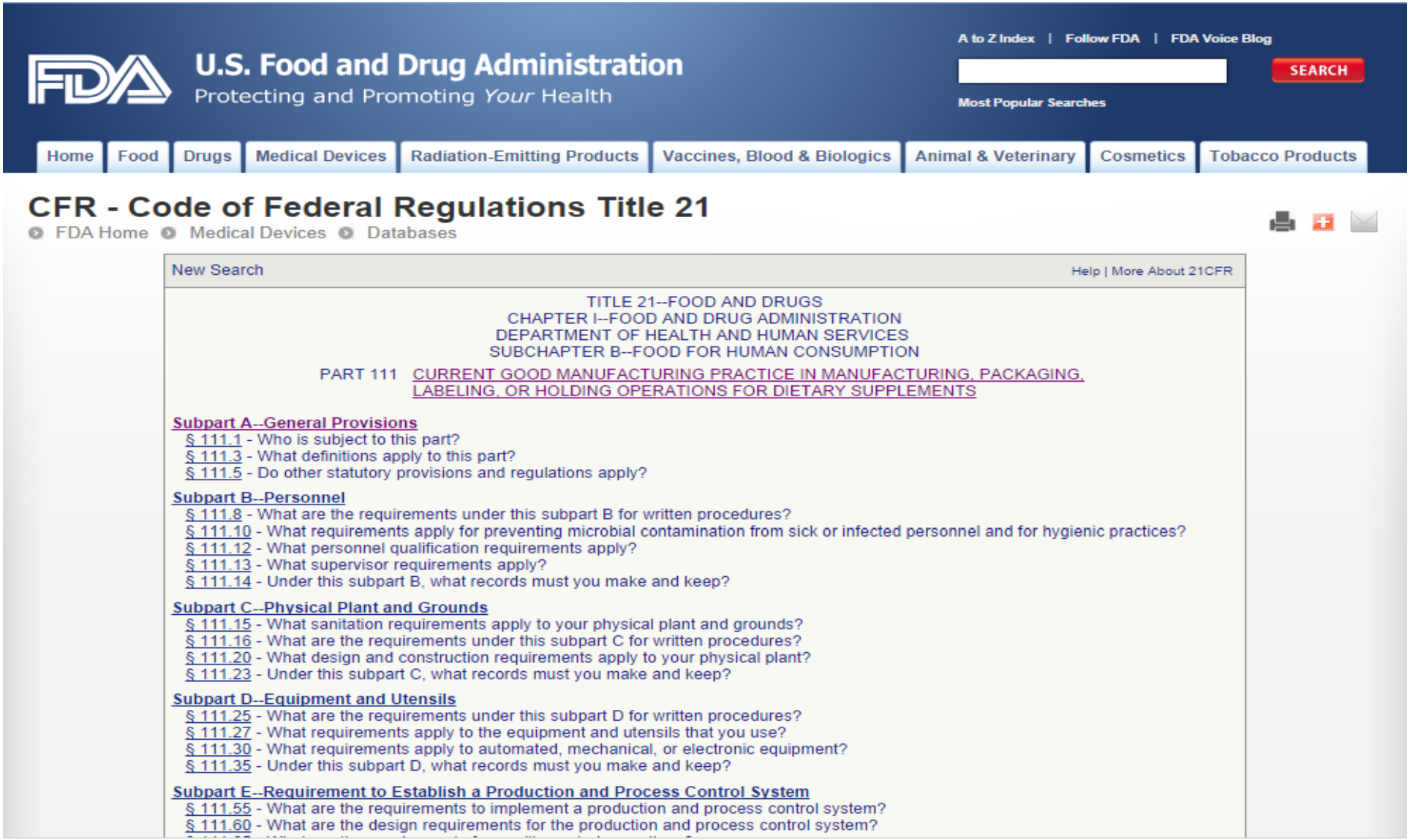
- Salt concentration of the product
  - 3,3% Hypertonic (only seawater)
  - 2,1% Hypertonic (seawater + spring water)
  - 0,9% Isotonic (seawater + spring water)

Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

GMP dietary supplements

If these are dietary supplements, what GMP did you apply?



http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=111

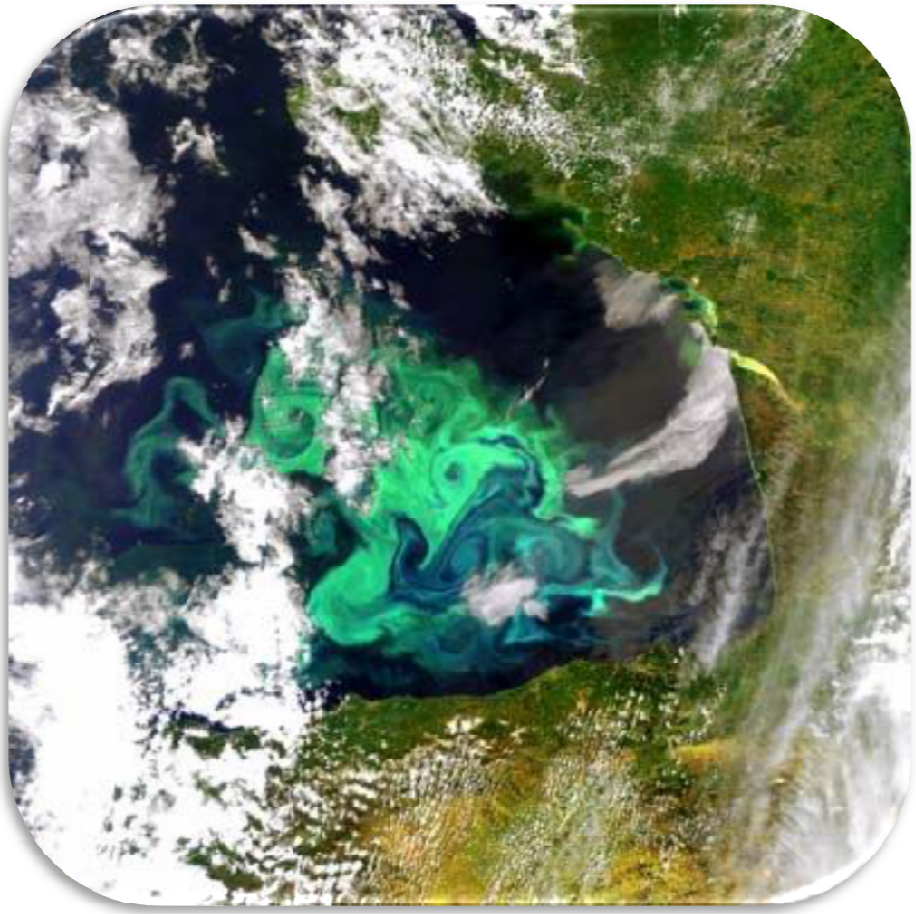
Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - –Applications during the process
- Audit and non-conformities
- Conclusion

Application during process

- Raw materials.





Application during process

- Raw materials.

How do we apply the GMP in this case?

Application during process

- Raw materials.
  - Transport
  - Sample
  - Storage (3-8 ºC)





Application during process

ALKEMI Laboratorio de Análisis y Consultoría

ASSAY RESULT: 705544

Sea water

SAMPLE DATA		GUSTOMER DATE
Sample type:	Raw material	LAB.QUINTON INTERNACIONAL, S.L.
Product (Description):	Sea water	C/ Annot, 6. Pol. Ind. Virgen de Carmen
Consumer code:	Lot: MP-1-139	3350 - Cox (ALICANTE)
Date of collection: 21/02/14 Amount sampled: 2 litros.		
Admition Date:	25/02/14	
Beginning Date:	25/02/14	
Ending Date:	24/03/14	
Sample delivered by:	CLIENTE Micro with Tiosulfate	Atto. Juan Jose Alberola

PHYSIC-CHEMICAL DATA

PNT	ANALYTICAL PARAMETER	UNITS	RESULT
AQ-357	Conductivity	µs/cm	48000
AQ-325	Disolved solids	mg/L	31200
	Salinity	‰	31,2
AQ-366	PH	Und. pH	8,1
AQ-413	Sodium chloride	mg/L	34300
AQ-320	PAHs	µg/L	See Comments
AQ-396	Materia Orgánica Total	mg O2/L	1350
AQ-362	Fluorides	mg/L	0,65
AQ-654	Potassium	mg/L	352
AQ-652	Calcium	mg/L	403
AQ-306	Sulfates	mg/L	2800
AQ-353	Chlorides	mg/L	20800
AQ-651	Sodium	mg/L	10139
AQ-653	Magnesium	mg/L	1110
AQ-321	Bicarbonate	mg/L	135
AQ-378	Nonionic detergents	mg/L	< 2,5
AQ-393	Cationic detergents	mg/L	< 0,10
AQ-327	Anionic detergents	mg/L	< 0,1
AQ-315	Turbidity	UNF	0,8
AQ-499	Organo-halogenated compounds	mg/L	0,10
	Acrylamide	µg/L	< 0,1
	Epichlorohydrin	µg/L	< 0,1
	Vinyl Chloride	µg/L	< 0,5
AQ-109	Lead	µg/L	< 2,5
AQ-682	Mercury	µg/L	< 0,5
AQ-401	Cooper	mg/L	< 0,1
AQ-410	Arsénic	µg/L	< 2,5
AQ-109	Cadmium	µg/L	< 0,5
AQ-354	Tin	mg/L	< 2
AQ-629	Barium	mg/L	< 1
AQ-324	Cyanides	µg/L	< 20
AQ-308	Nitrites	mg/L	< 0,050
AQ-665	Zinc	mg/L	< 0,1
AQ-312	Sulfides	mg/L	2,34
AQ-681	Selenium	µg/L	< 2,5

ALKEMI Laboratorio de Análisis y Consultoría

ASSAY RESULT: 705544

Sea water

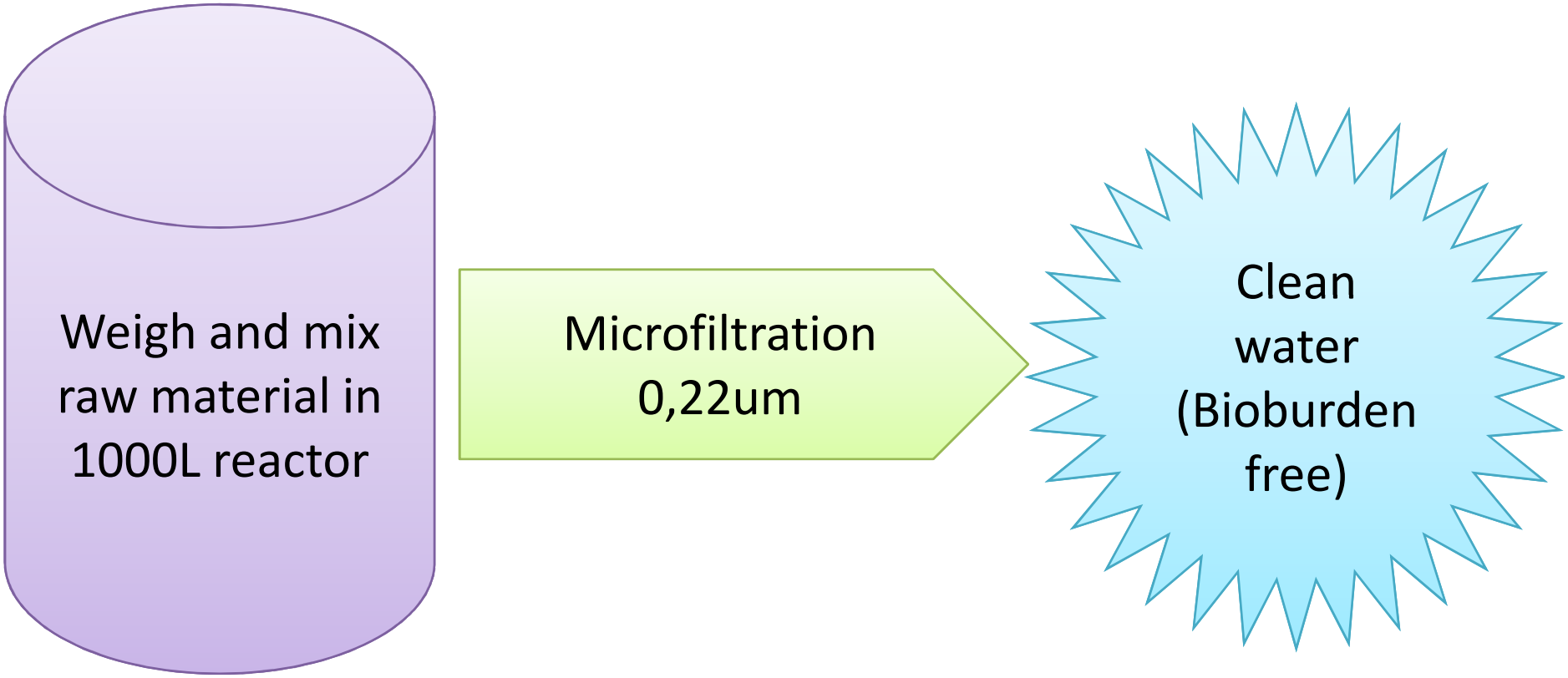
PHYSIC-CHEMICAL DATA

PNT	ANALYTICAL PARAMETER	UNITS	RESULT
AQ-358	Chrome VI	mg/L	< 0,050
AQ-316	Nitrates	mg/L	< 2
AQ-323	Boron	mg/L	4,6
AQ-612	Manganese	mg/L	< 0,05
AQ-355	Antimony	µg/L	< 2,5

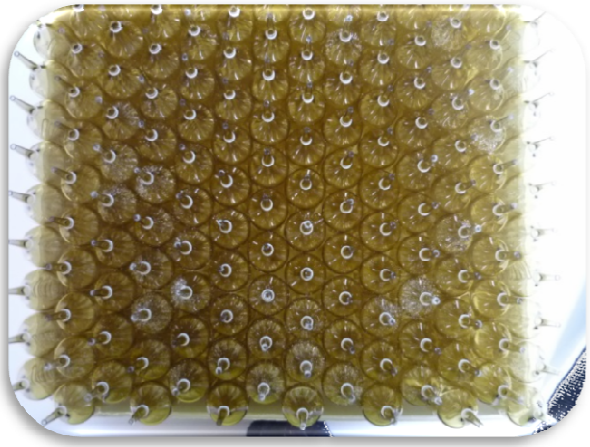
MICROBIOLOGICAL DATA

PNT	ANALYTICAL PARAMETER	UNITS	RESULT
AM-100	Aerobic mesophilic 22 ° C. Count	ufc/ml	9,8E+01
AM-100	Aerobic mesophilic 37 ° C. Count	ufc/ml	2,8E+01
AM-115	Total coliforms, Count	u fc/100ml	0
AM-119	Streptococcus D. Lancefield, count	u fc/100ml	0
AM-104	Clostridium perfringens, count	u fc/100ml	0
AM-120	*Pseudomonas aeruginosa , count*	u fc/100ml	0
AM-111	Salmonella-Shigella, Research	---	Absence/100 ml
	Burkholderia cep acea		Absence
AM-121	Candida albicans, Research	ufc/100ml	0
AM-117	*Staphylococcus aureus;* count	ufc/100ml	0
AM-101	*Molds and yeasts* count	ufc/ml	1,1 E+01
AM-709	Pesticides (Organophosphates Carbamates +)	---	Negative
AM-112	Enterobacteriaceas, Count	ufc/ml	< 1
AM-134	Escherichia coli , Count	ufc/100ml	0
AM-144	*Listeria monocytogenes*, Research	---	Absence /100 ml
	Vibrio sp	---	Absence /100 ml

Application during process



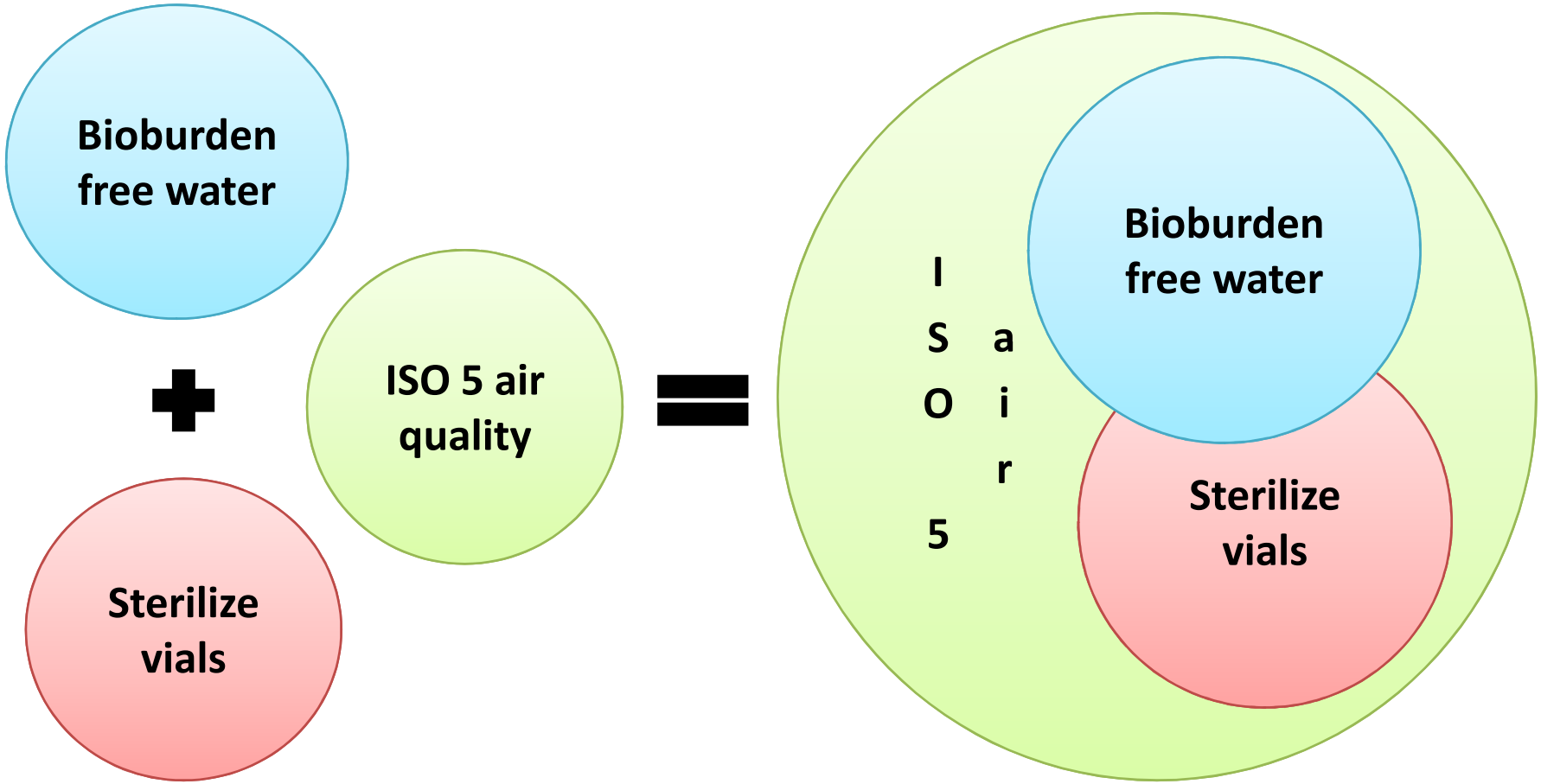
Application during process



Dry hot oven
120ºC 6h



Application during process



Application during process

- Filling process.

How do we apply the GMP in this case?

Application during process

- Annual calibration of the reactor.



- Annual clean room validation.

Clase de partículas contenidas en el aire para salas limpias según norma UNE-EN-ISO 14644-1						
Nº clasificación N de ISO	Valor máximo de la concentración de partículas					
	0,1µm	0,2µm	0,3µm	0,5µm	1,0µm	5,0µm
Clase ISO 4	10000	2370	1020	352	83	-
Clase ISO 5	100000	23700	10200	3520	832	29
Clase ISO 6	1000000	237000	102000	35200	8320	293
Clase ISO 7	-	-	-	352000	83200	2930
Clase ISO 8	-	-	-	3520000	8320000	29300

Application during process

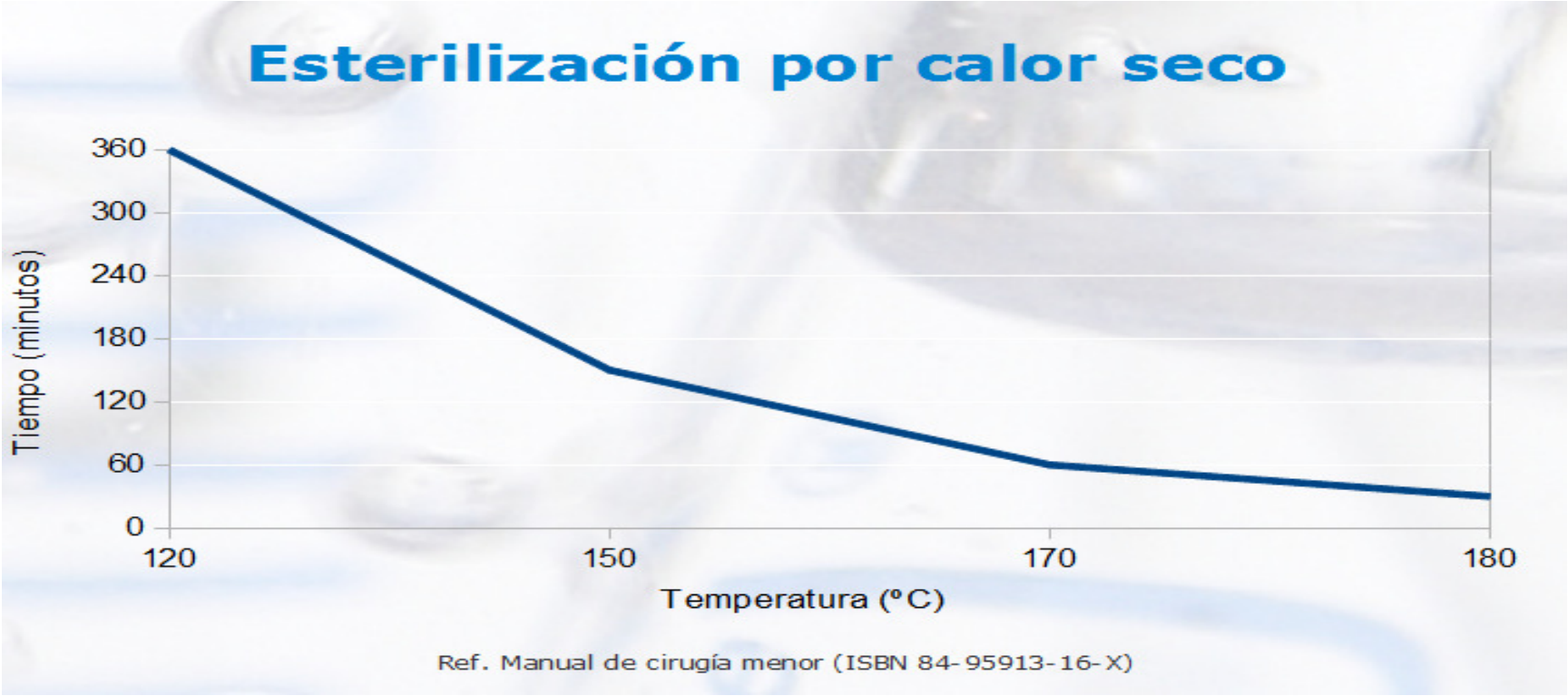
- Filtration.
  - Sterilize the filters
  - Bubble point after manufacture





Application during process

- Oven validated annually



Application during process

- Final product validation



QUINTON

LABORATOIRES QUINTON INTERNATIONAL

INFORME DE ENSAYO : IMQ12/14

DATOS DE LA MUESTRA

Matriz: COMPLEMENTO ALIMENTICIO

Producto (descripción): QUINTON HYPERTONIC 10mL

Referencias (Lote): JH-01

Fecha de fabricación: 10/01/2014

Nº Muestra: N.A.

Nº Análisis: 14/22

Fecha de Recepción: 27/01/14

Fecha Inicio de Análisis: 27/01/2014

Fecha Fin de Análisis: 03/02/2014

Recogido por: Juan Francisco Seller

ENSAYOS MICROBIOLOGÍA

PNT	DETERMINACIONES	UNIDADES	RESULTADO	CRITERIO
M-604	Aerobios mesófilos a 37 ºC, Recuento	ufc/ml	<1	< 10.000
M-604	Aerobios mesófilos a 22 ºC, Recuento	ufc/ml	<1	< 10.000
M-604	Hongos y Levaduras, Recuento	ufc/ml	<1	< 100
M-604	Enterobacteriáceas, Recuento	ufc/ml	<1	< 100
M-604	*Escherichia coli*, Investigación	---	AUSENCIA	AUSENCIA/ml
M-604	*Salmonella/Shighella spp*, Invest.	---	AUSENCIA	AUSENCIA/10ml
M-604	*Staphylococcus aureus*, Investigación	---	AUSENCIA	AUSENCIA/ml
M-604	*Pseudomona aeruginosa*, Investig.	---	AUSENCIA	AUSENCIA/ml
M-604	*Candida Albicans*, Investigación	---	AUSENCIA	AUSENCIA/ml

Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

Audit and non-conformities

USLF108

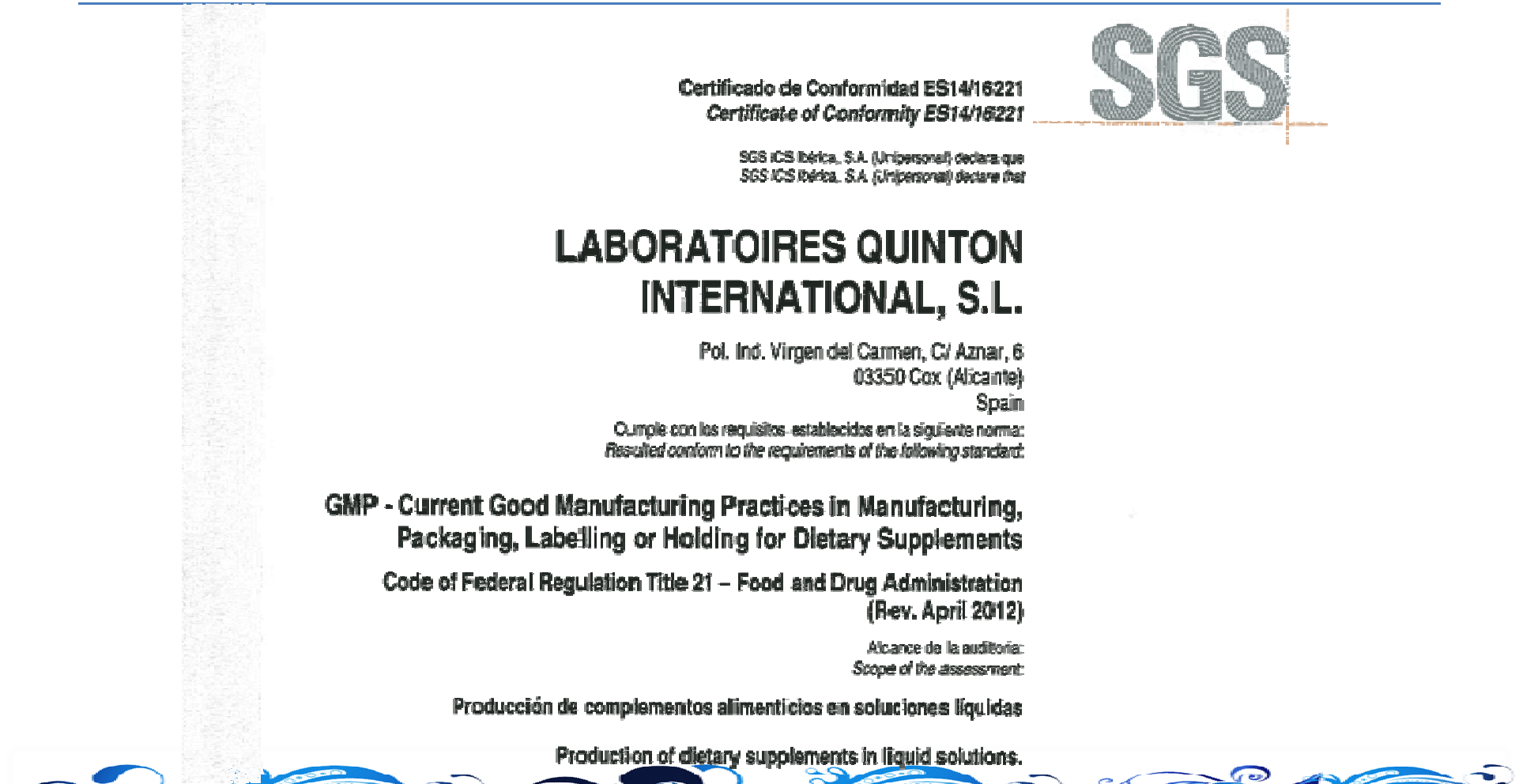
Dietary Supplement cGMP Certification
Audit Report

Organization:	LABORATOIRES QUINTON INTERNATIONAL		
Address:	Pol. Ind. Virgen del CarmenC/ Aznar, 6, Cox (Alicante)		
Standard(s):	☒ cGMP Dietary Supplement - 21CFR 111 version June 2007 ☐ Codex Alimentarious Food Hygiene CAC/RCP 1-1969		
Accreditation Body(s) :			
Representative:	María Pellín	Title:	
Site(s) audited:	Pol. Ind. Virgen del CarmenC/ Aznar, 6, Cox (Alicante)	Date(s) of audit(s):	7 and 8/07/2014
No. of Employees:	40	No. of Shifts:	1
Lead auditor:	Eugenia Ligorit	Other team member(s):	
This report is confidential and distribution is limited to the audit team, client representative and the SGS office.			

Minor

No.	Requirement ref.	Details of non-conformity	Corrective action taken	Cause of Non Conformity and proposed action plan	Date reviewed	Reviewed & Accepted by
1	111.25	Se detecta que no se dispone de los últimos registros del mantenimiento semanal para algunos equipos clave (por ejemplo, la llenadora DOGOMO). Tampoco se ha documentado un mantenimiento preventivo interno para el sistema de aire de la sala blanca o para las infraestructuras.				

Audit and non-conformities



Certificado de Conformidad ES14/16221
Certificate of Conformity ES14/16221

SGS ICS Ibérica, S.A. (Unipersonal) declara que
SGS ICS Ibérica, S.A. (Unipersonal) declare that

LABORATOIRES QUINTON INTERNATIONAL, S.L.

Pol. Ind. Virgen del Carmen, C/ Aznar, 6
03350 Cox (Alicante)
Spain

Cumple con los requisitos establecidos en la siguiente norma:
Resulted conform to the requirements of the following standard:

GMP - Current Good Manufacturing Practices in Manufacturing, Packaging, Labelling or Holding for Dietary Supplements

Code of Federal Regulation Title 21 – Food and Drug Administration (Rev. April 2012)

Alcance de la auditoría:
Scope of the assessment:

Producción de complementos alimenticios en soluciones líquidas

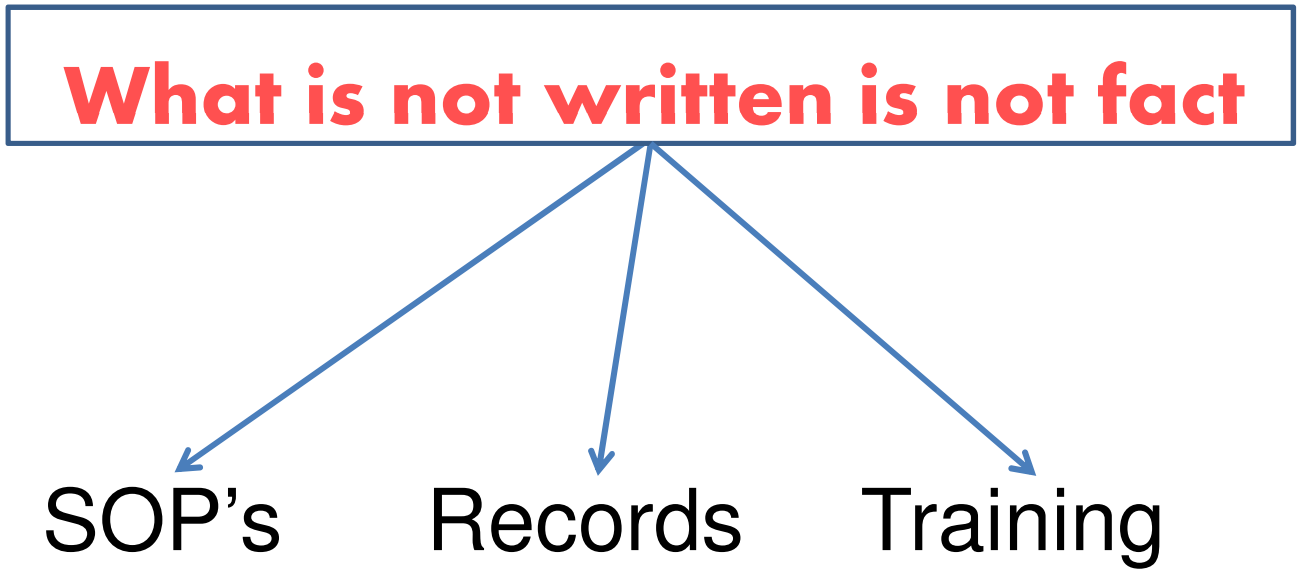
Production of dietary supplements in liquid solutions.

Index

- Who are we?
- Advance Quinton Protocol
- GMP dietary supplements
  - Applications during the process
- Audit and non-conformities
- Conclusion

Conclusion

GMP



Conclusion











Thanks for your attention

María Pellín Amorós

mpellin@quinton.es