



“It is a truth universally acknowledged, that a single man in possession of a good fortune, must be in want of a wife.”



“It is a truth universally acknowledged, that a single man in possession of a good fortune, must be in want of a wife.”

Jane Austen



ISO 10993-1: A matchmaker guide

FOR A BIOLOGICALLY SAFE RELATIONSHIP BETWEEN A MEDICAL DEVICE AND A PATIENT

Lise Vanderkelen - 26 APRIL 2023



CONFIDENTIAL

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EXPERTS

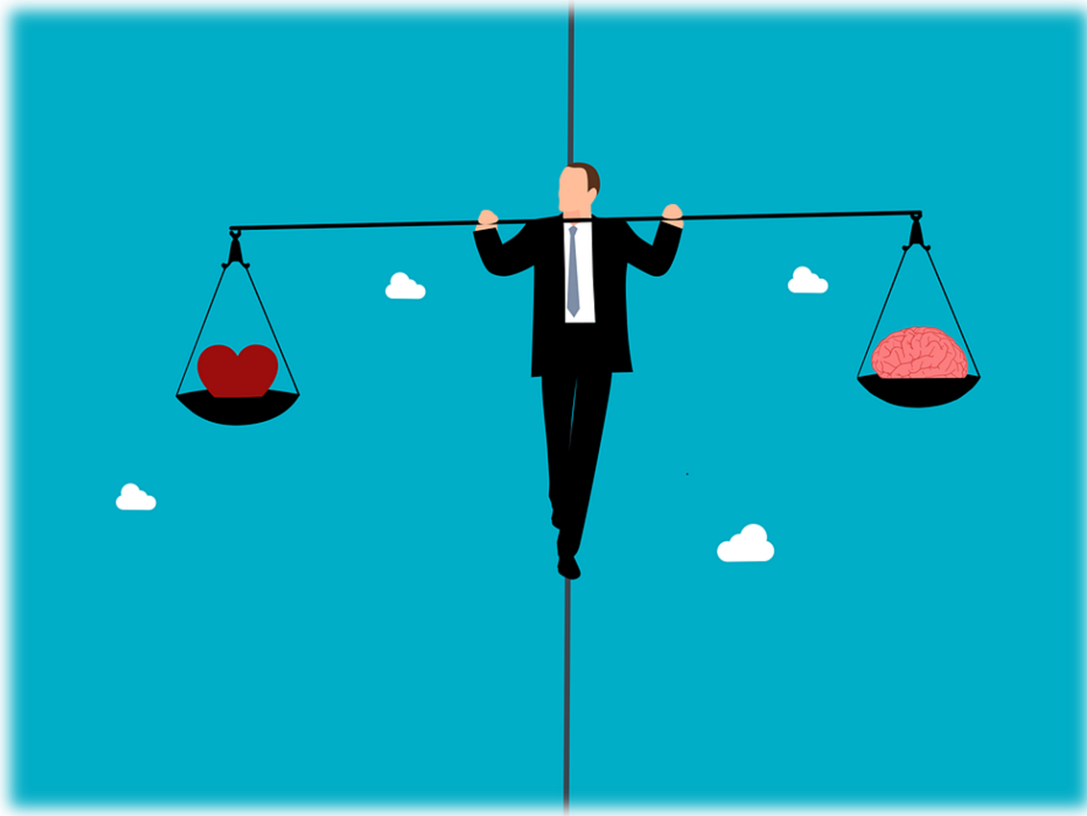


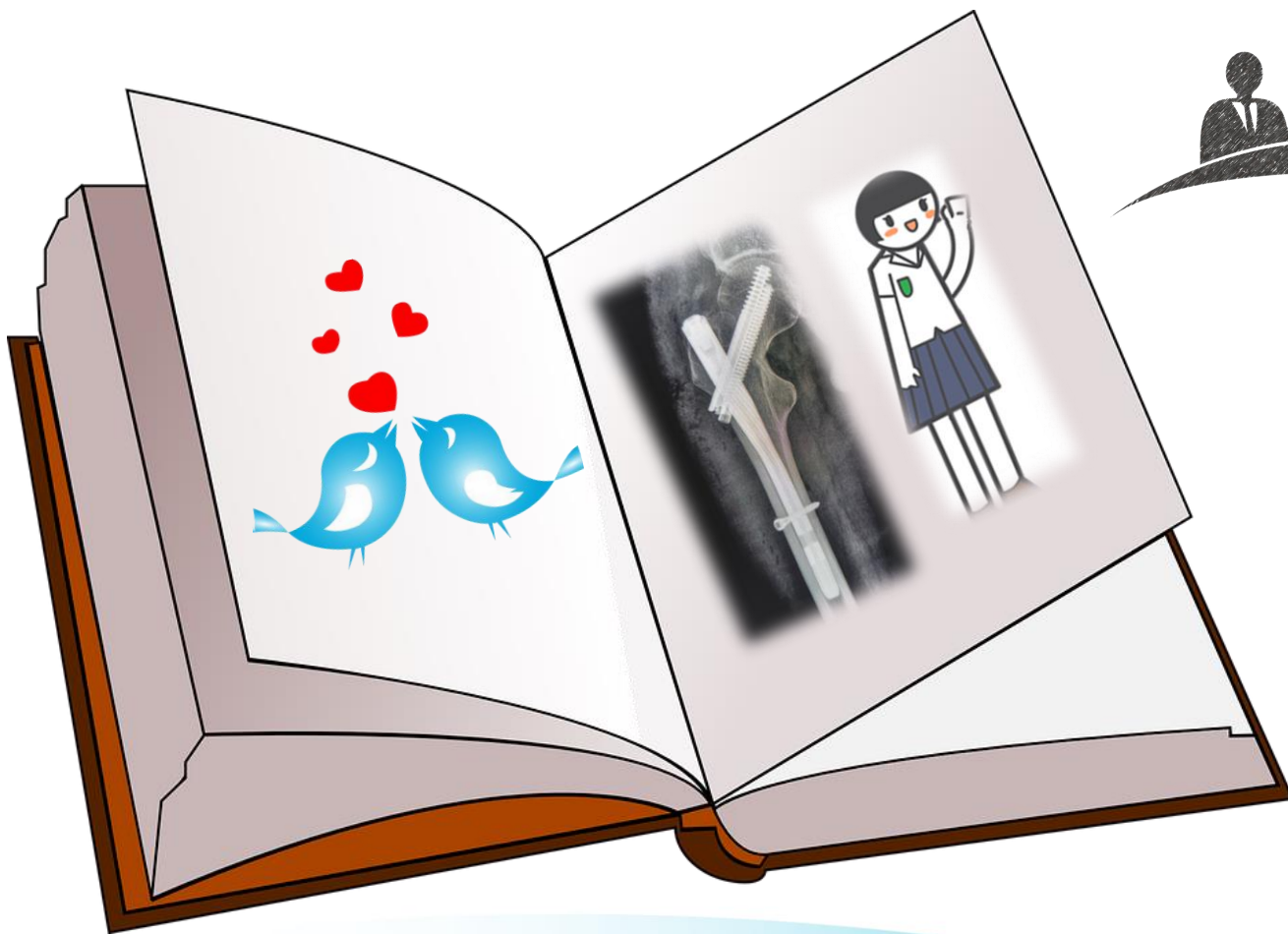
PATIENT

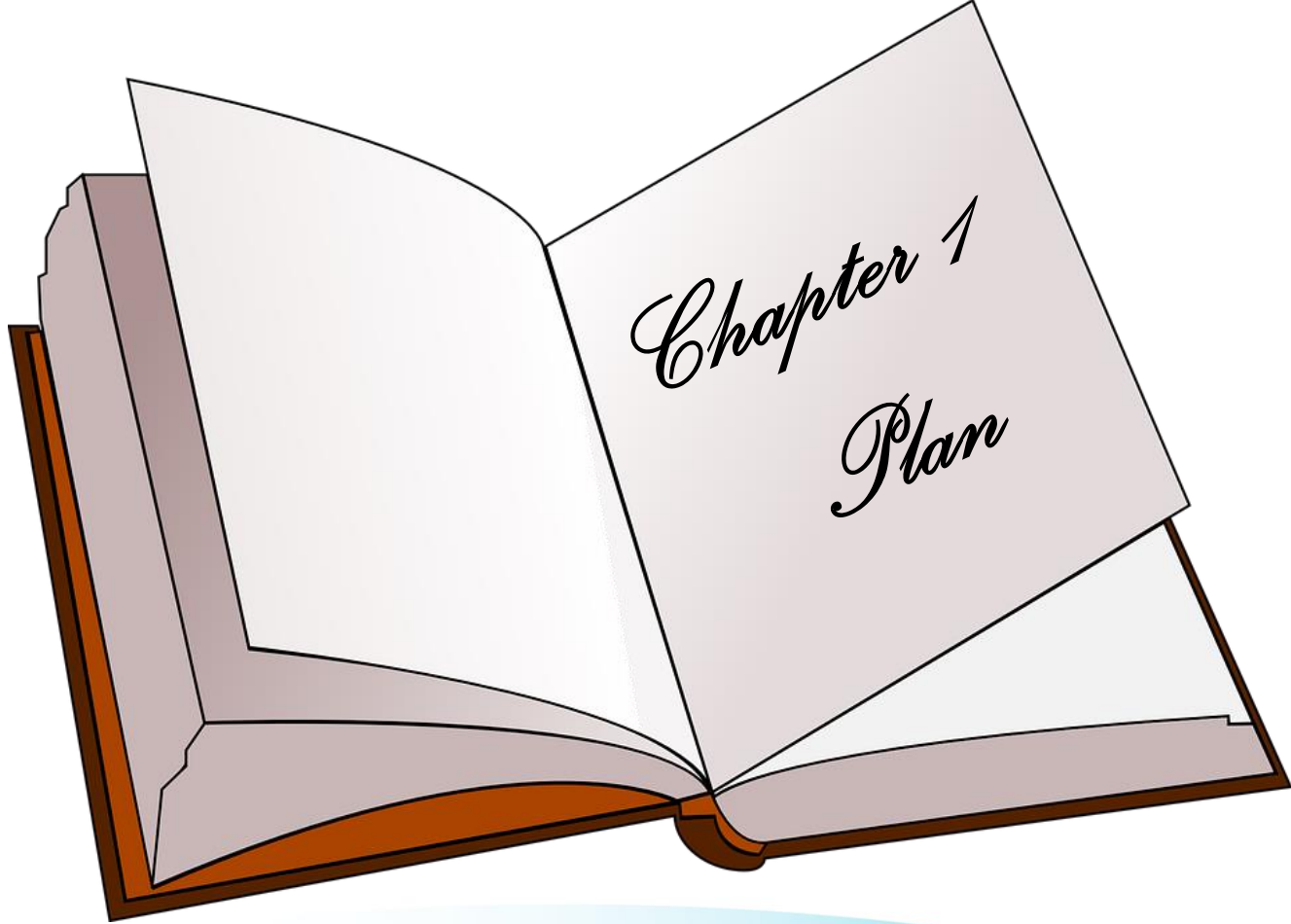


MEDICAL DEVICE









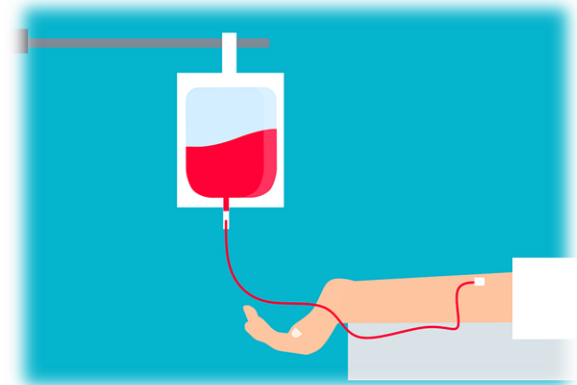
Get to know your device



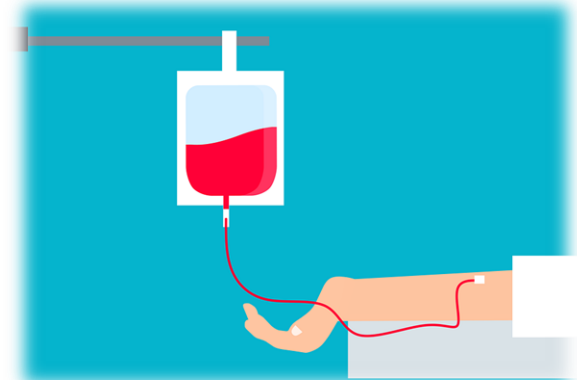
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Get to know your device → CATEGORY

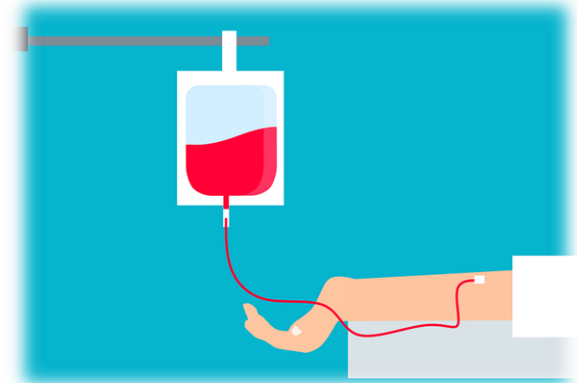






























Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation																
Nature of body contact		Contact duration	Physical and/or chemical information	Cyto toxicity	Sensitization	Irritation or intra cutaneous reactivity	Ma-terial media ted pyro geni city ^a	Acute syste mic toxici ty ^b	Sub acu te toxici ty ^b	Sub chro nic toxici ty ^b	Chro nic toxici ty ^b	Impla nta tion ef-fects- ^{b,c}	Hem oco mpa tibili ty	Gen otox icity ^d	Car cin oge nic ity ^d	Repro ductive/ develop mental toxici ty ^{d,e}	Deg rada tion ^f		
Category	Contact	A - limited (≤24 h) B - prolonged (>24 h to 30 d) C - Long term (>30 d)																	
Surface medical device	Intact skin	A	X ^g	E ^h	E	E													
		B	X	E	E	E													
		C	X	E	E	E													
	Mucosal membrane	A	X	E	E	E							E						
		B	X	E	E	E		E	E				E						
		C	X	E	E	E		E	E	E	E	E	E		E				
	Breached or compromised surface	A	X	E	E	E	E	E					E						
		B	X	E	E	E	E	E	E				E						
		C	X	E	E	E	E	E	E	E	E	E	E		E	E			
Externally communicating medical device	Blood path, indirect	A	X	E	E	E	E	E					E						
		B	X	E	E	E	E	E	E				E						
		C	X	E	E	E	E	E	E	E	E	E	E	E	E				
	Tissue/ bone/ dentin ⁱ	A	X	E	E	E	E	E											
		B	X	E	E	E	E	E	E				E		E				
		C	X	E	E	E	E	E	E	E	E	E	E		E	E			
	Circulating blood	A	X	E	E	E	E	E						E	E ^j				
		B	X	E	E	E	E	E	E				E	E	E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E	E			

Endpoints of Biological evaluation

Physical and/or Chemical information	Cytotoxicity	Sensitization	Irritation	Material Mediated Pyrogenicity	Acute Systemic toxicity	Sub acute toxicity	Sub chronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive toxicity	Degradation
X	F	F	F	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)
														

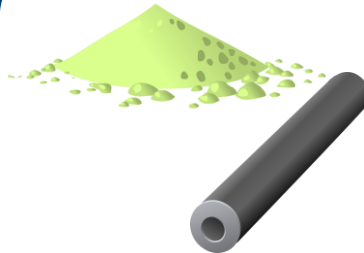
Endpoints of Biological evaluation

Physical and/or Chemical information	Cytotoxicity	Sensitization	Irritation	Material Mediated Pyrogenicity	Acute Systemic toxicity	Sub acute toxicity	Sub chronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive toxicity	Degradation
X	F	F	F	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)	(F)
														

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Use

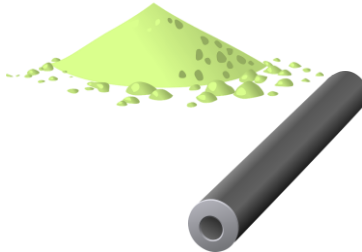


Materials

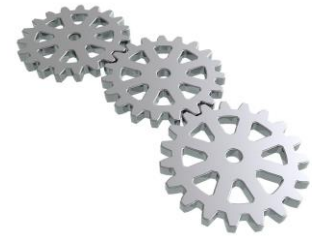
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Use

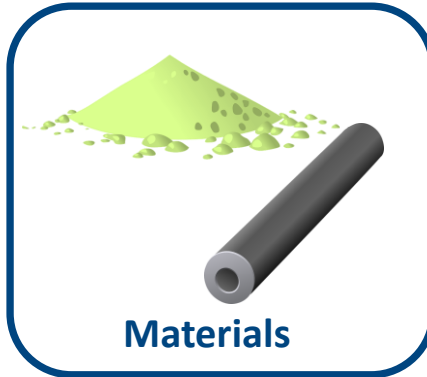


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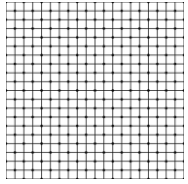


Manufacturing

Get to know your device



Get to know your device



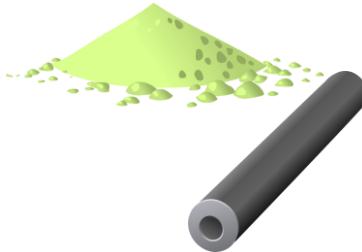
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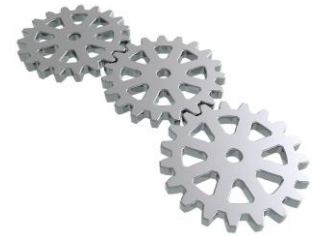
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Packaging

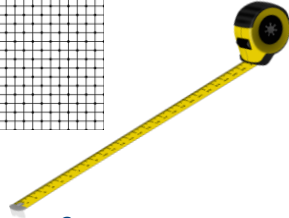
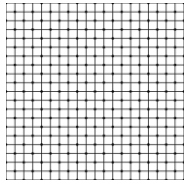


Materials



Manufacturing

Get to know your device



Configuration



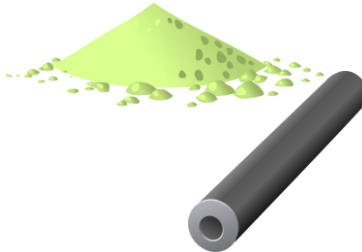
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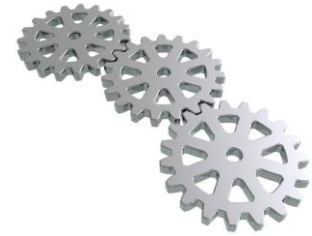
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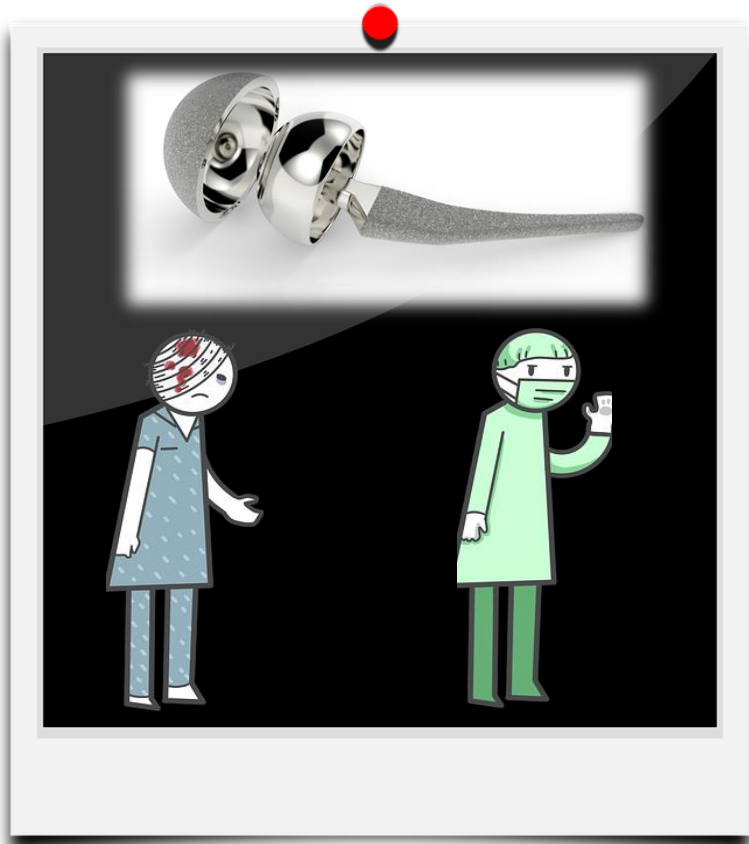
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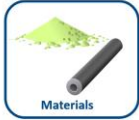
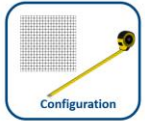
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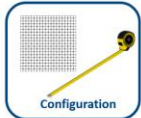


Manufacturing









Configuration



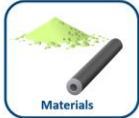
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Historical data



Packaging



Materials

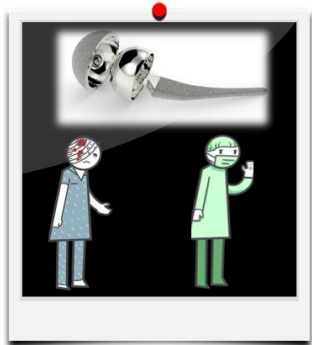
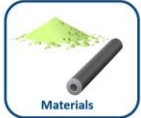


Manufacturing



Endpoints of Biological evaluation

Physical and/or Chemical information	Cytotoxicity	Sensitization	Irritation	Material Mediated Pyrogenicity	Acute Systemic toxicity	Sub acute toxicity	Sub chronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive toxicity	Degradation
X	E	E	E	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)





Configuration



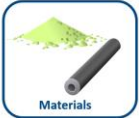
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Historical data



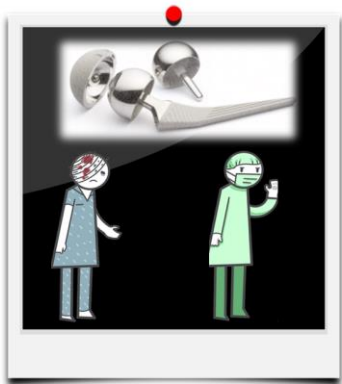
Packaging



Materials



Manufacturing



E&L testing



***In vitro* tests**



***In vivo* tests**



Configuration



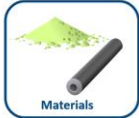
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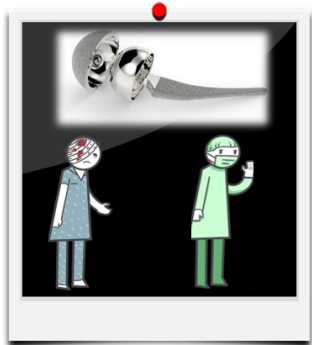
Packaging



Materials



Manufacturing



BIOLOGICAL EVALUATION PLAN

DEVICE:

X

SPONSOR:

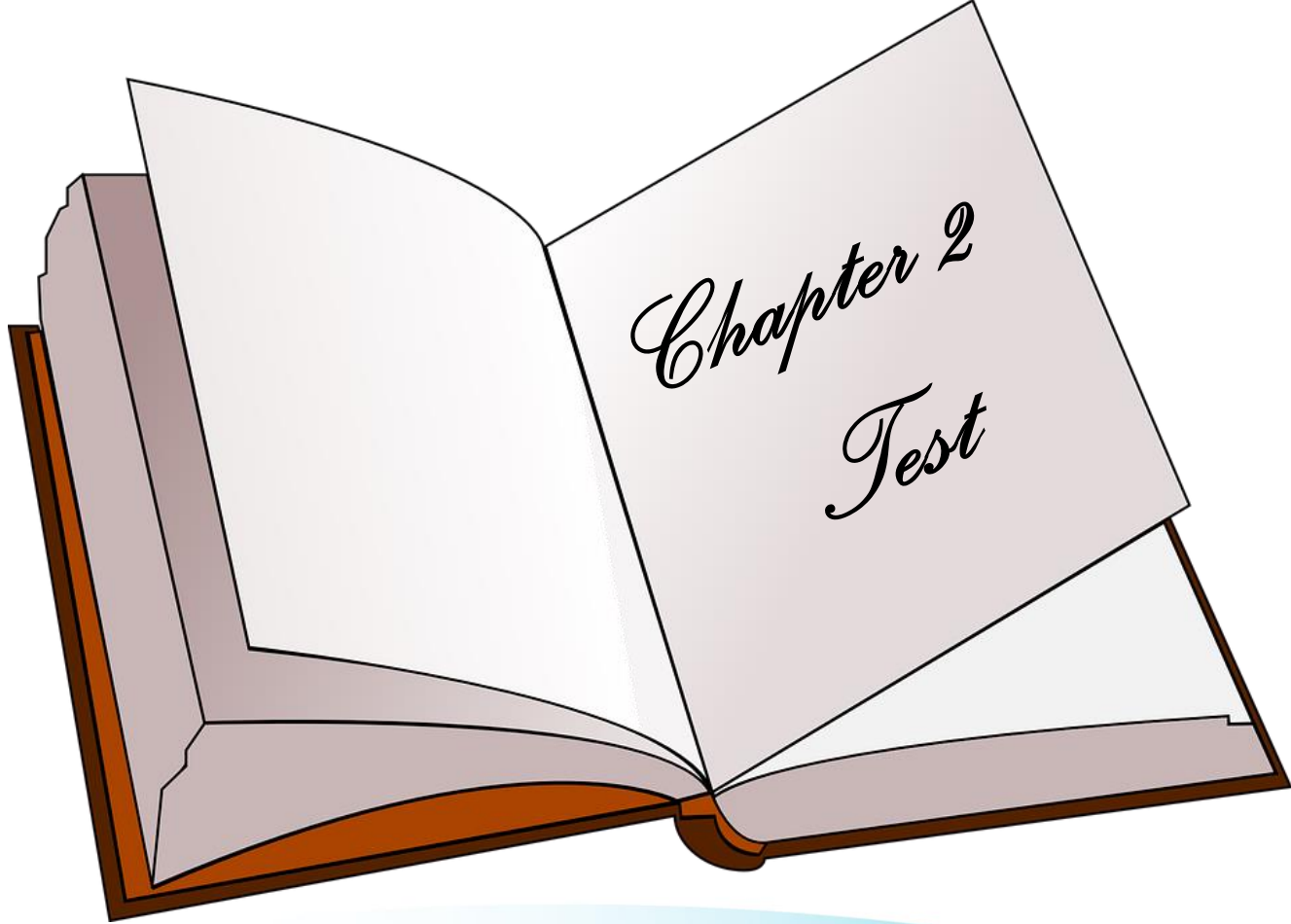
X

PROJECT#:

X

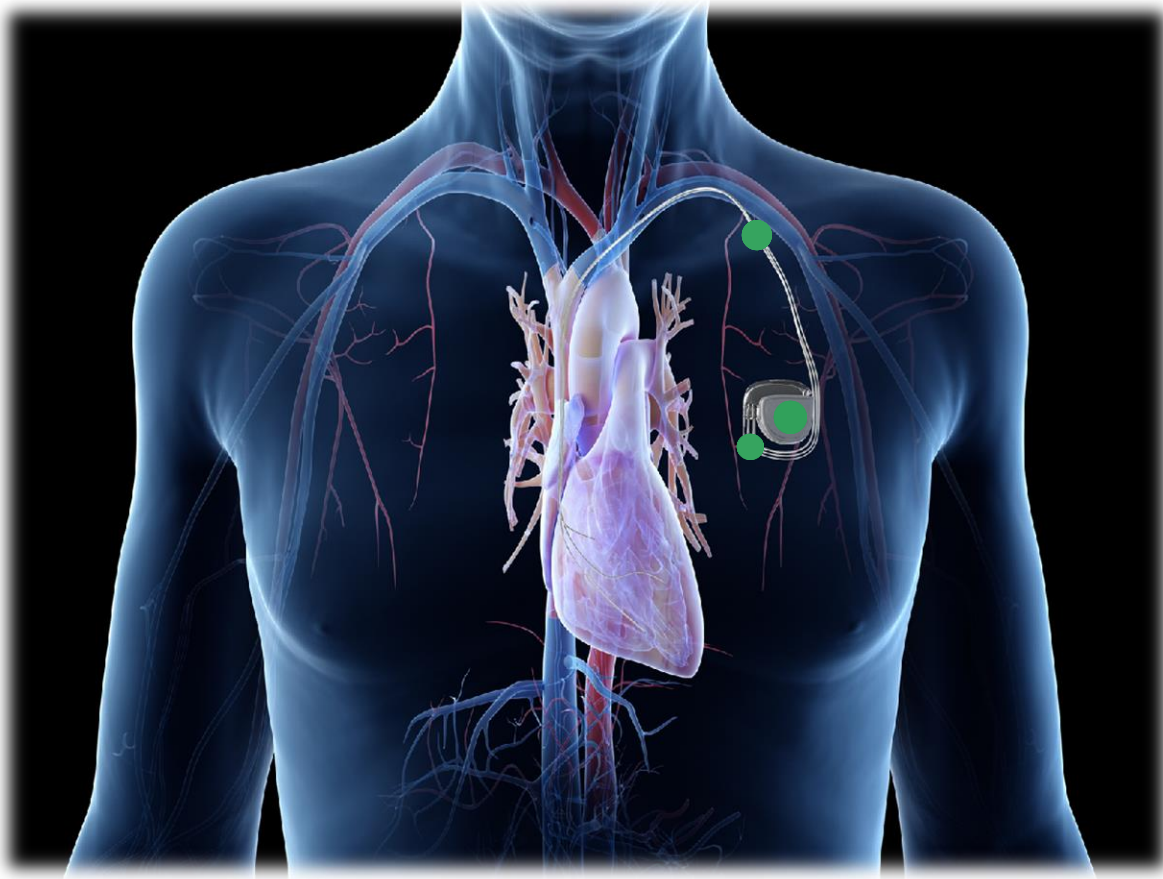
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How to create chemistry between the device and the patient?



How to create chemistry between the device and the patient?



ISO 10993-18 Chemical characterization of materials

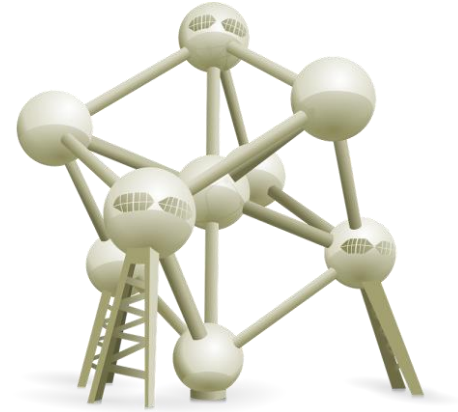
Ans De Roeck

&

Looking into the Future of Extractable testing

Piet Christiaens

How to create chemistry between the device and the patient?



Good Identification Practices

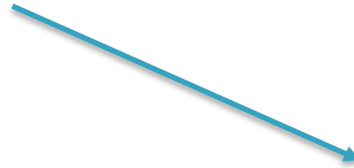
Ward D'Autry

How to create chemistry between the device and the patient?

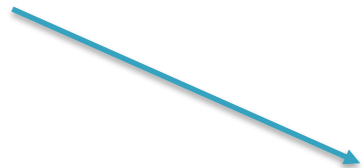
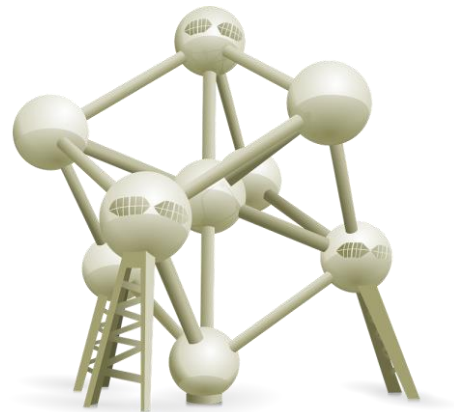


Current and Novel Approaches in the Quantitation Strategy

Dennis Jenke

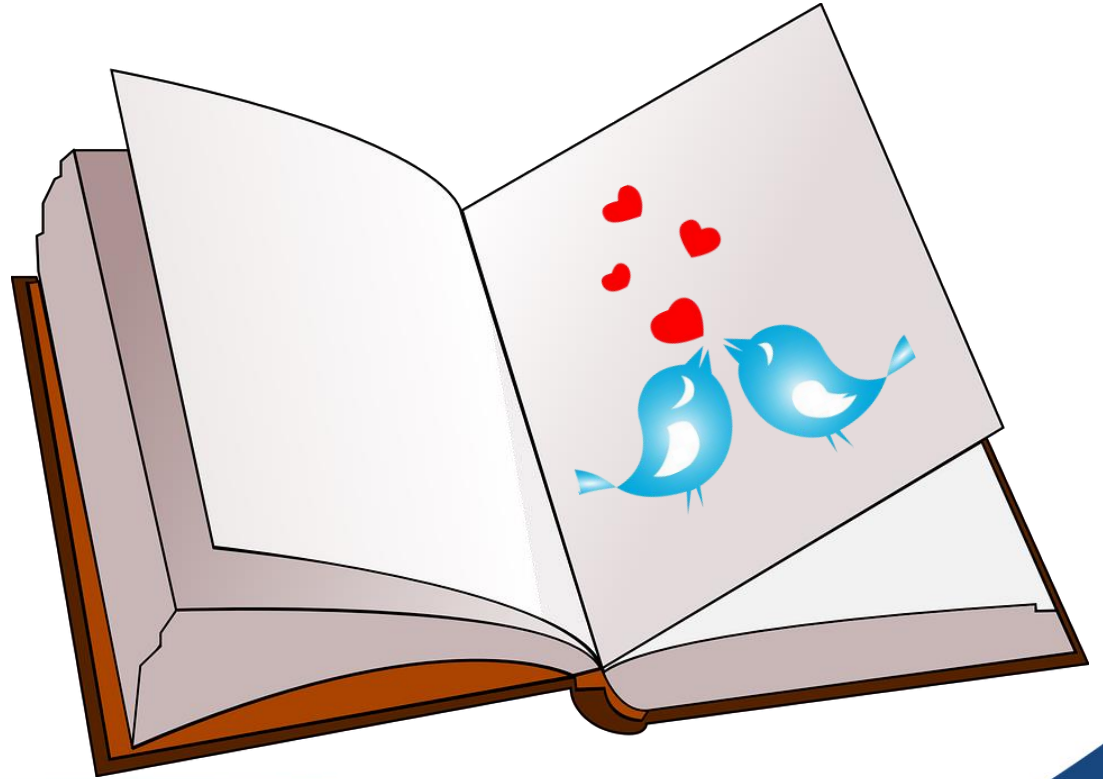
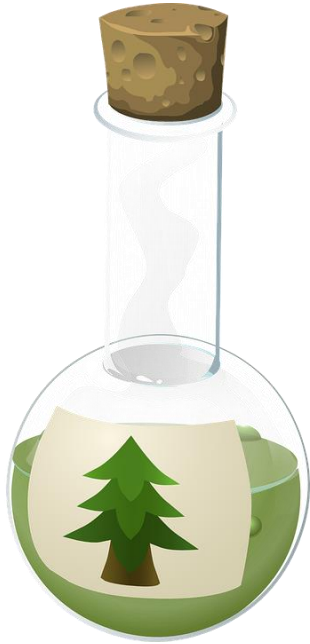


How to create chemistry between the device and the patient?





ISO 10993-17



















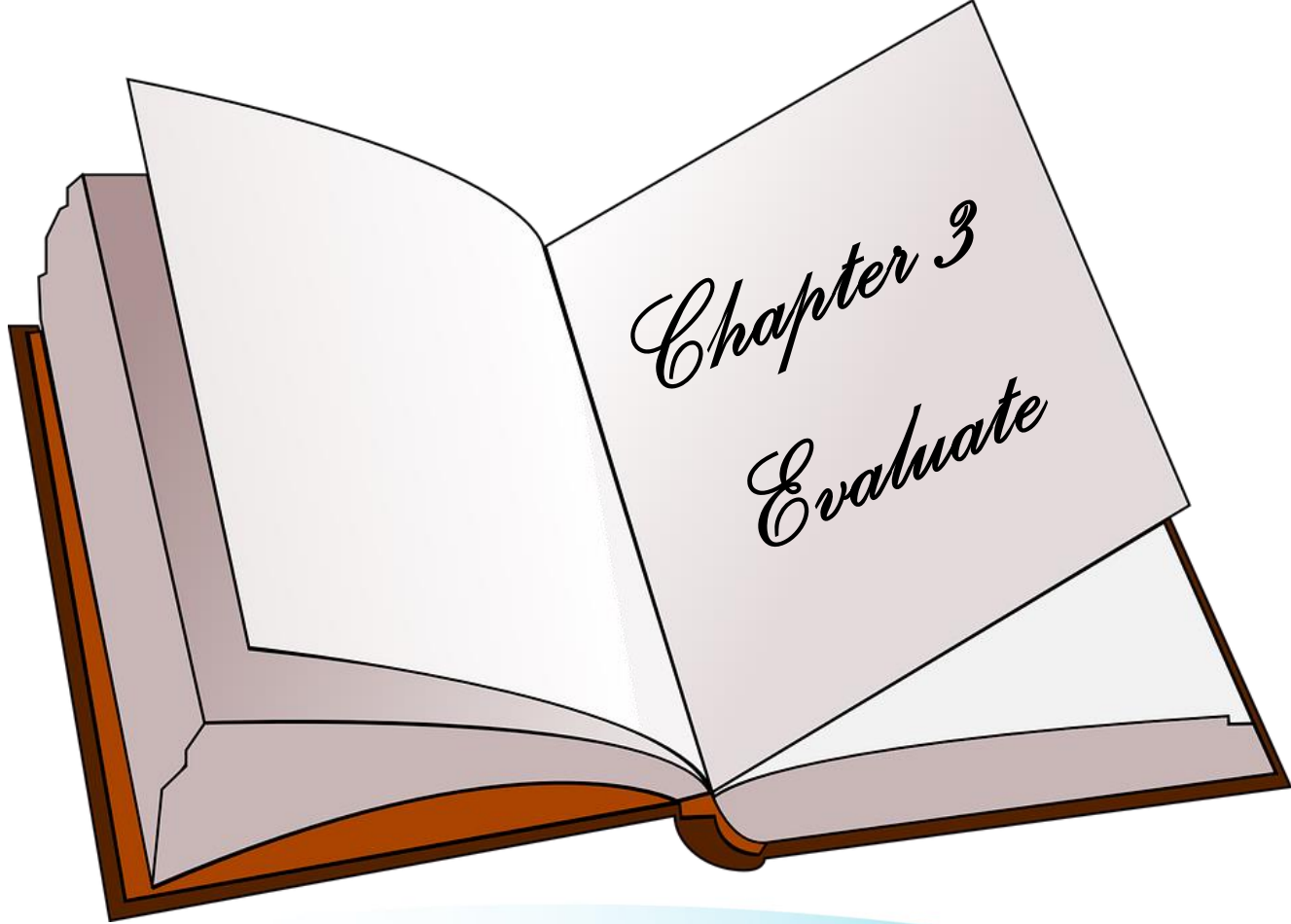


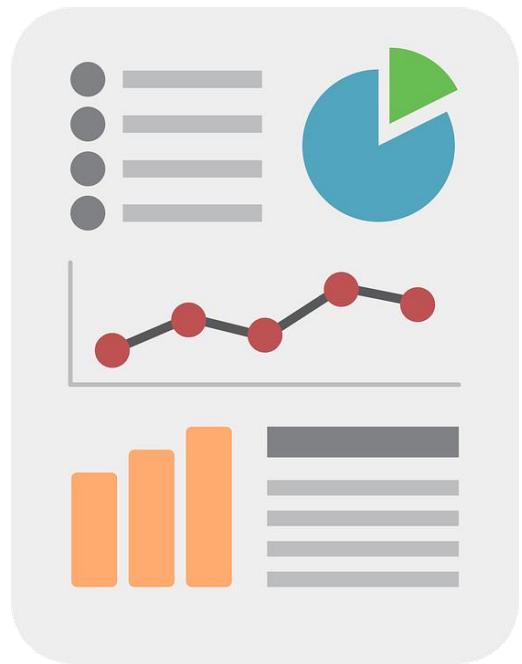
Extended “Coffee Break” discussing ISO 109993-17
Sherry Parker & Limulus Bio

Endpoints of Biological evaluation

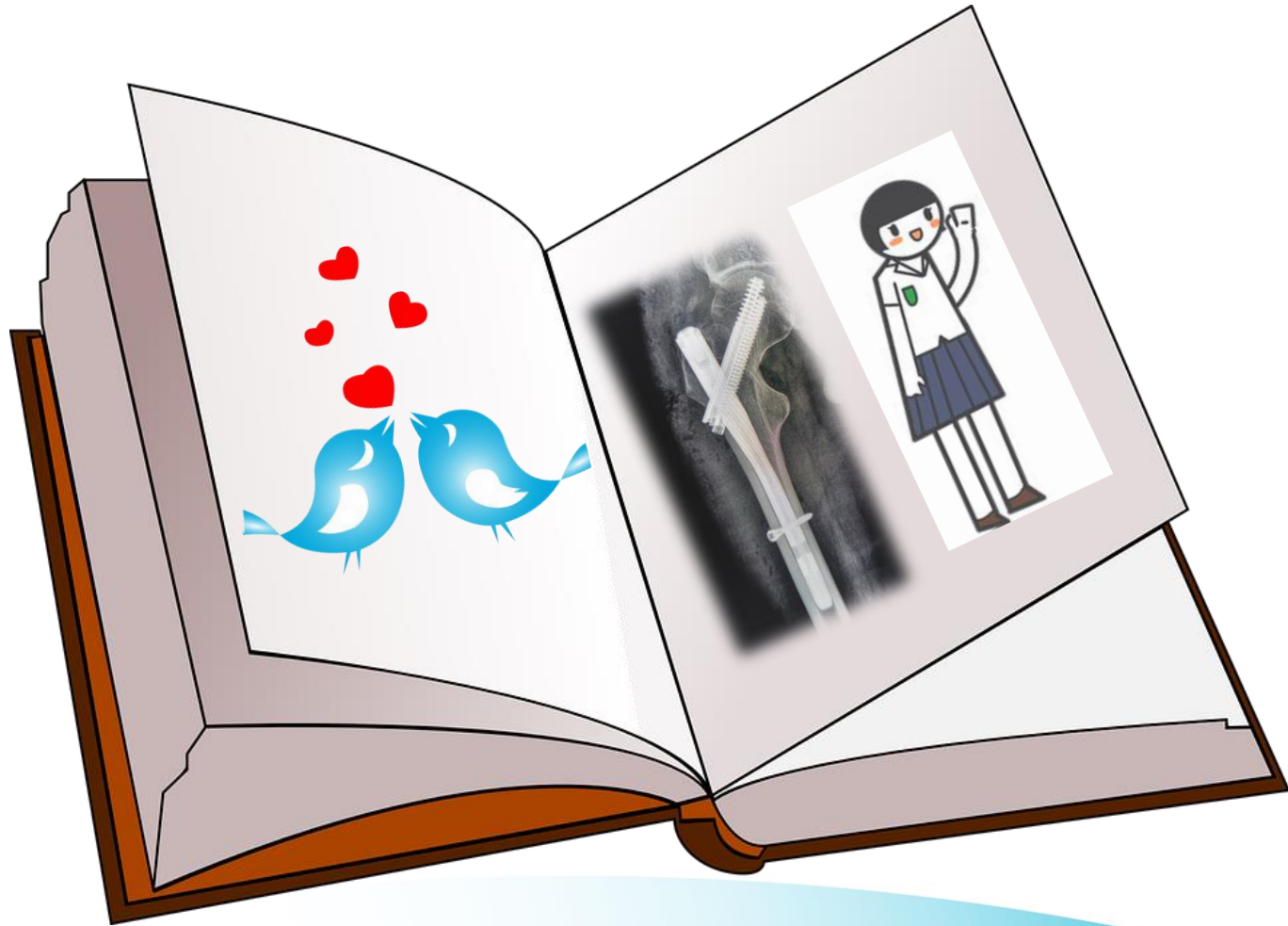
Physical and/or Chemical information	Cytotoxicity	Sensitization	Irritation	Material Mediated Pyrogenicity	Acute Systemic toxicity	Sub acute toxicity	Sub chronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive toxicity	Degradation
X	E	E	E	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(E)
														



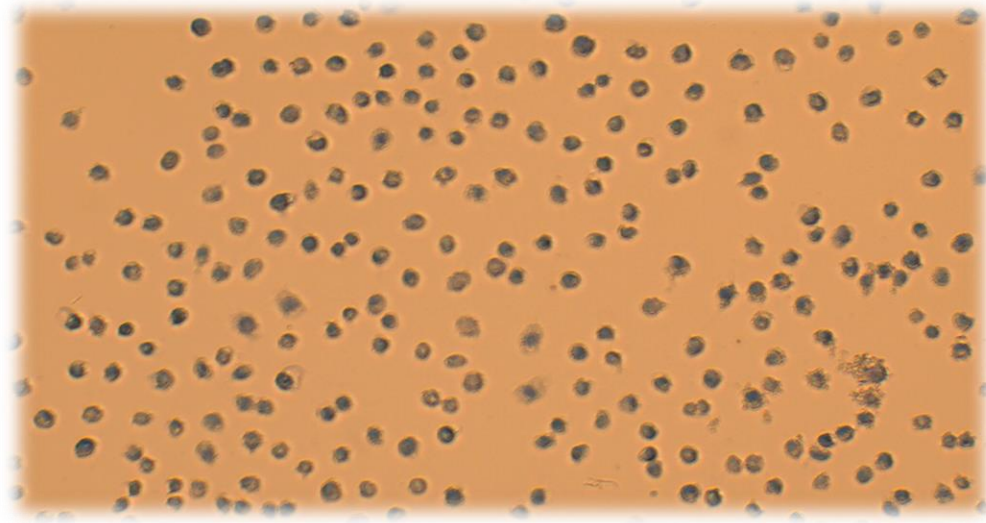




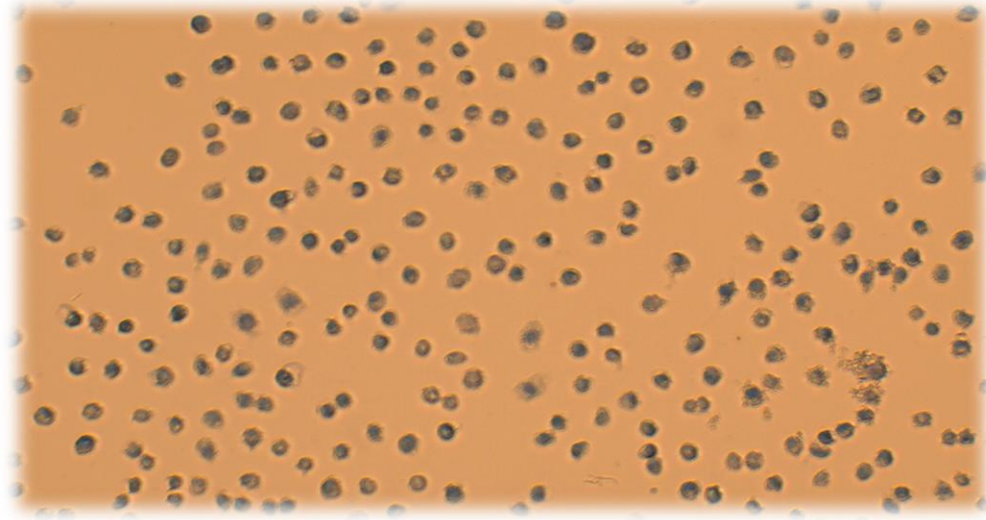




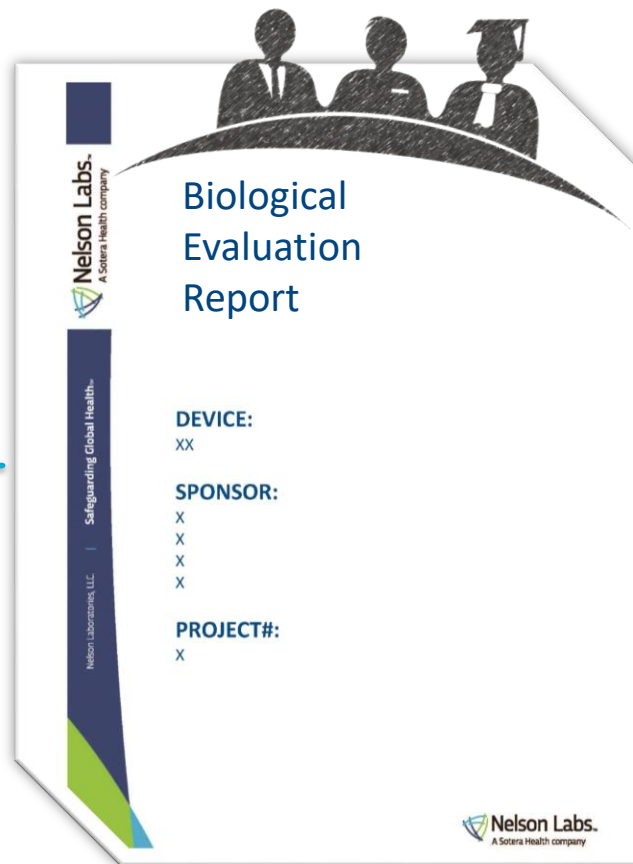
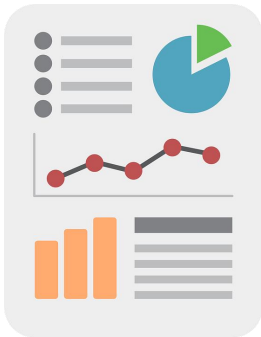
Cytotoxicity Failure

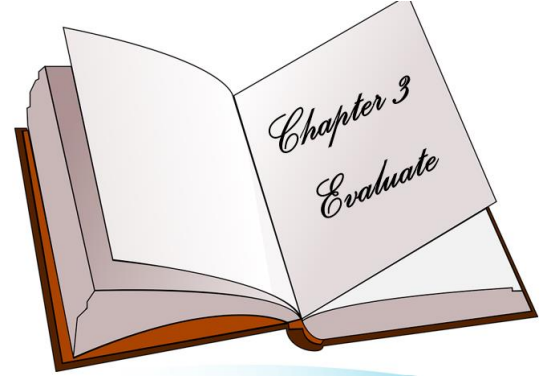
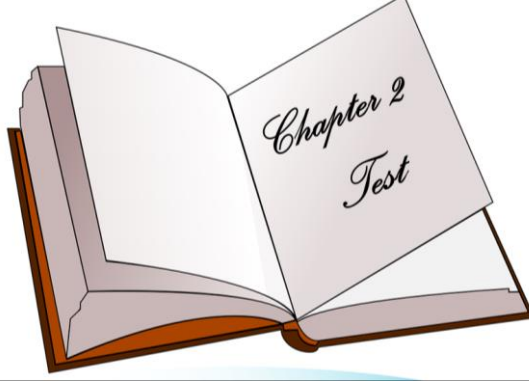
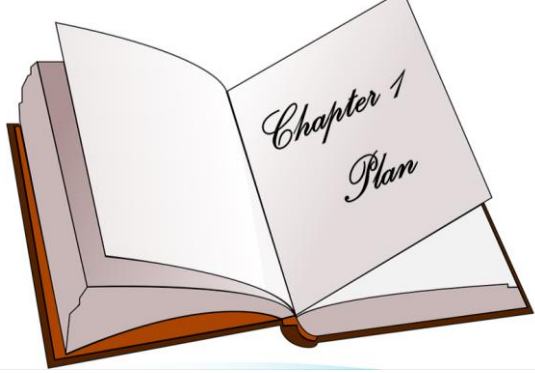


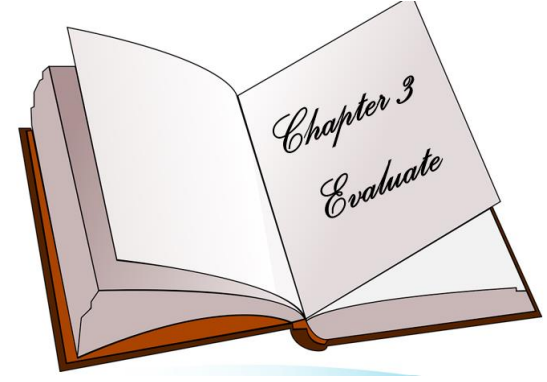
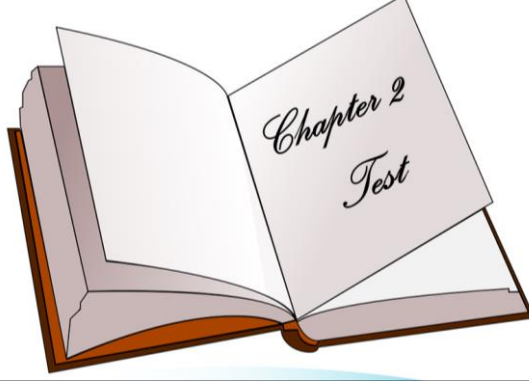
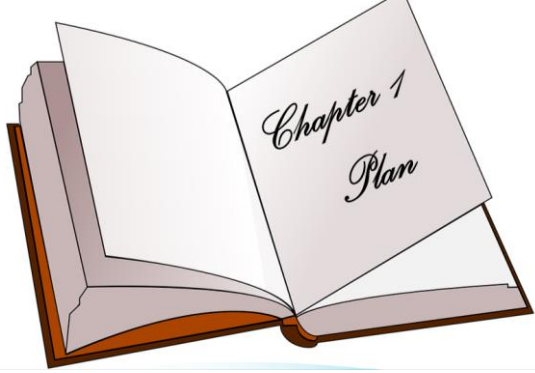
Cytotoxicity Failure



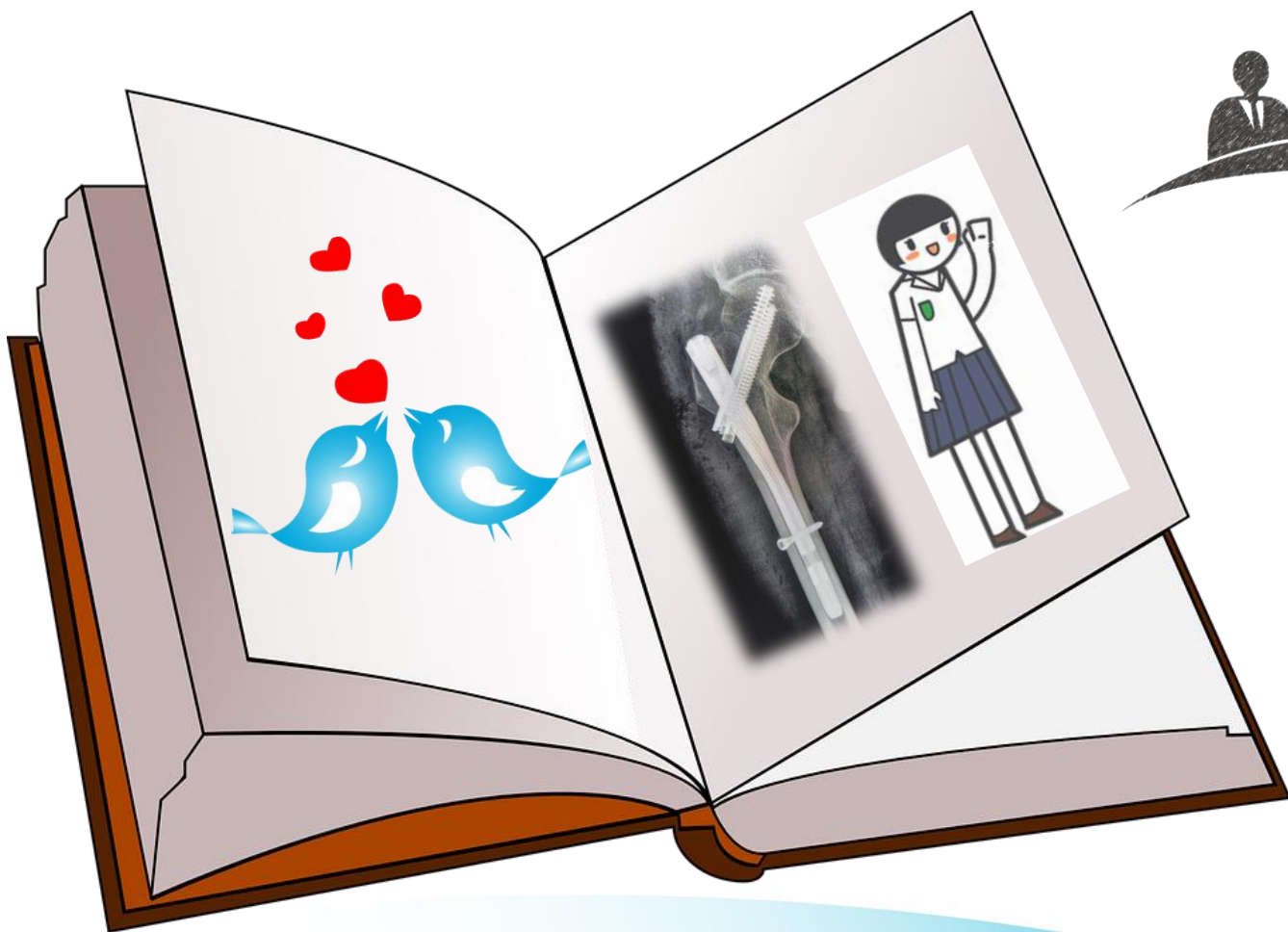








ISO 10993-1





“It is a truth universally acknowledged, that a medical device in possession of a good biosafety evaluation, must be in want of patients.”

lvanderkelen@nelsonlabs.com





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