



Consulting on Advanced Biologicals

Chair Intro

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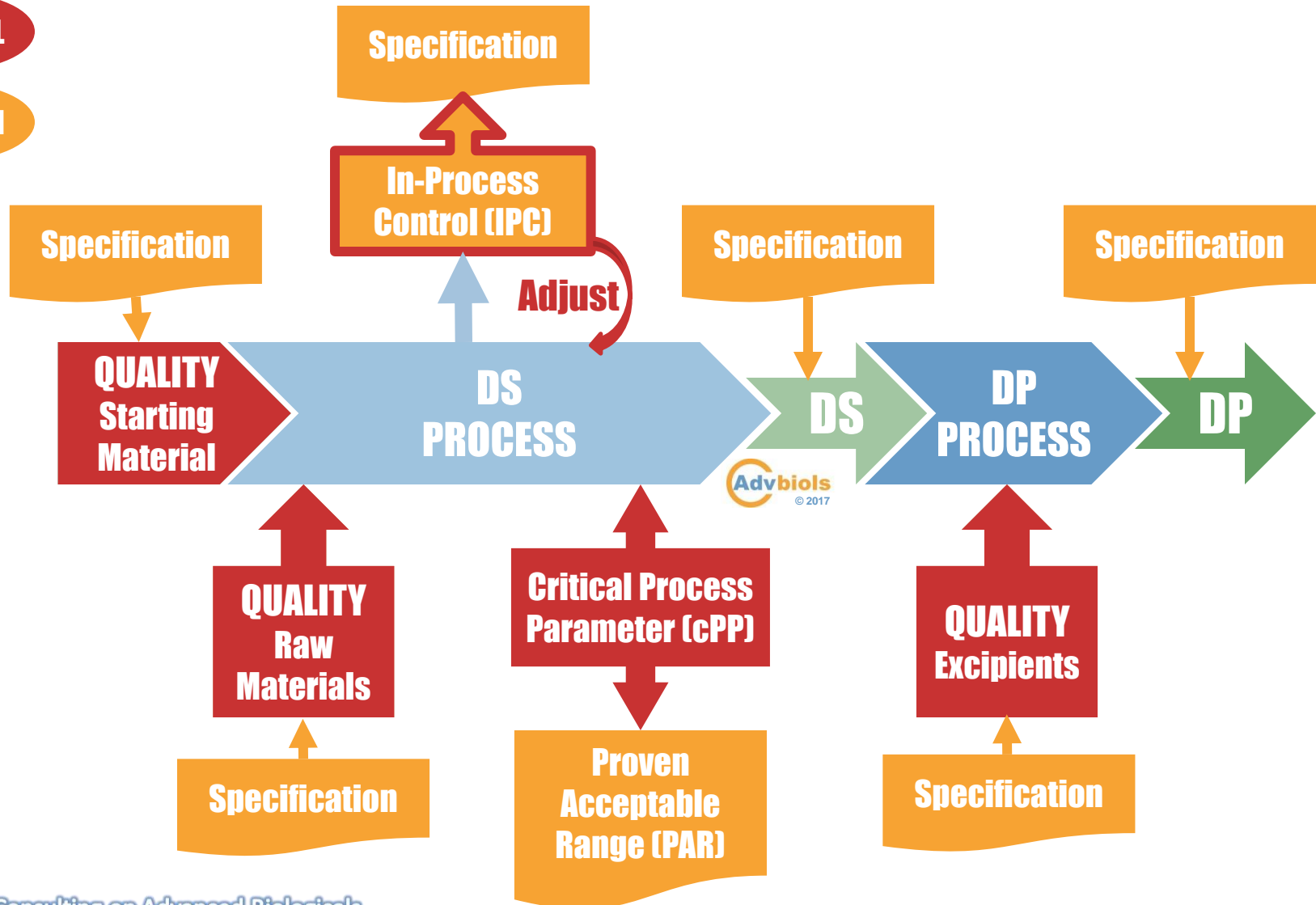
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COMPONENTS OF A CONTROL STRATEGY

Confirmation and Control

CONTROL

CONFIRM



BREAKDOWN OF ISSUES RAISED

ATMP SUBMISSIONS TO THE EMA SINCE 2001

	Gene Therapy Medicinal Product								Cell-based Medicinal Products							M	
	Cerepro	Advexin	Gendux	Cerepro#2	Glybera	Imlygic	Strimvelis	Zalmoxis	Heparesc	Holoclar	pherox	MAC	Provenge	Hyalograft C	OraNera	ChondroCelect	Apligraf
Process Control	M	M	M		M		O	X	M	M	M	M	M	M	X	X	M
Starting material							O		M _F						X		M
Raw materials quality/spec									O	M		X?	X	M			M
Intermediates										X				M		X	O
In-process testing							?		M	M		X?			X	X?	O
Process parameters											M			X	X	X?	O
Release testing	X	M			M		O	M	M	O	M	X	M	M	X	X	M
Justification of specifications		X	X		M			X	M _F	X	X _F	X	M	M	X		O



DRAFT RESULTS

BREAKDOWN OF ISSUES RAISED - METROLOGY

ATMP SUBMISSIONS TO THE EMA SINCE 2001



Gene Therapy Medicinal Product

Cell-based Medicinal Products

	Cerepro (2007)	Advexin (2007)	Gendux (2008)	Cerepro (2009)	Glybera (2009)	Imlygic (2014)	Strimvelis (2015)	Zalmoxis (2014)	Heparesc (2014)	Holoclar (2013)	Spherox (2013)	MACI (2011)	Provenge (2011)	Hyalograft C (2011)	OraNera (2011)	ChondroCelect (2007)
Method unsuitable (excl potency)					X									X		
Potency Unsuitable							X	X	X					X	X	
Validation								X _{FUM}	X					X		
Validation (excl potency)	X	X														
Validation of potency	X										X	X	X			