

Towards Vaccinating The World

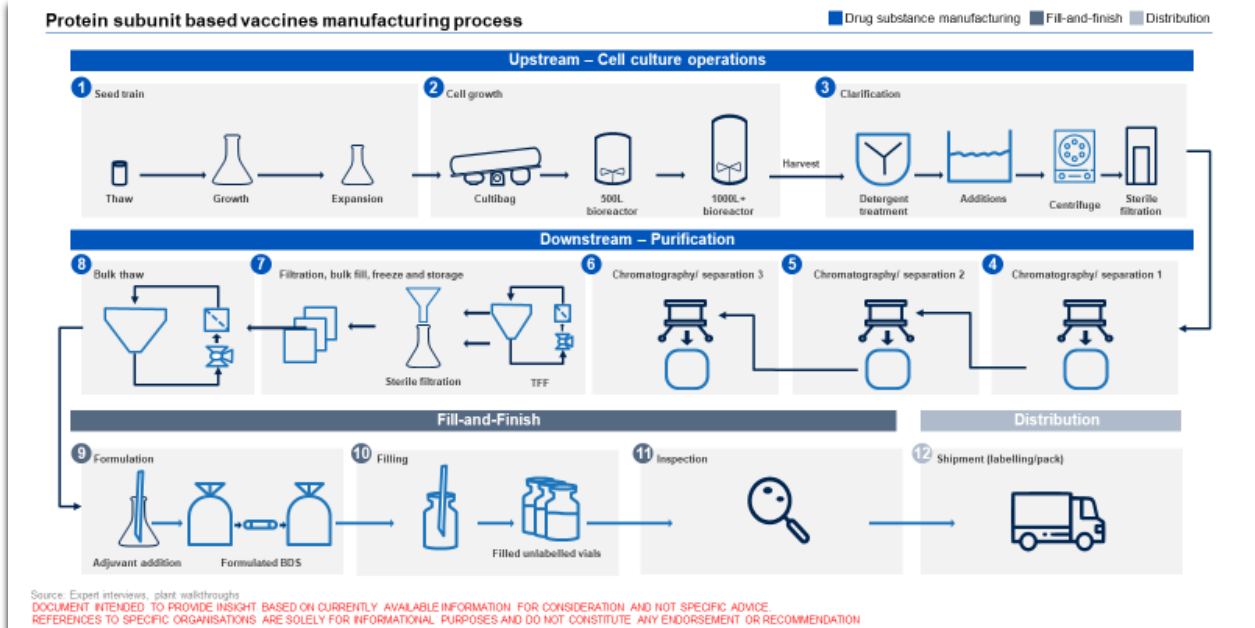
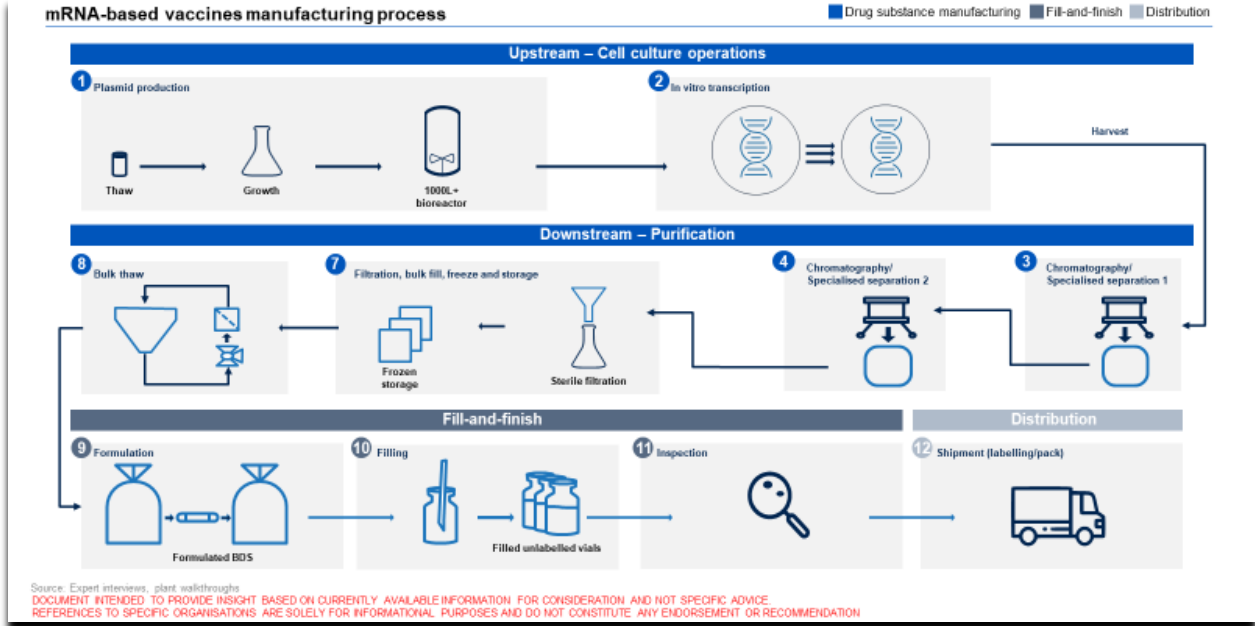
Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space”: a Discussion Document

Appendix

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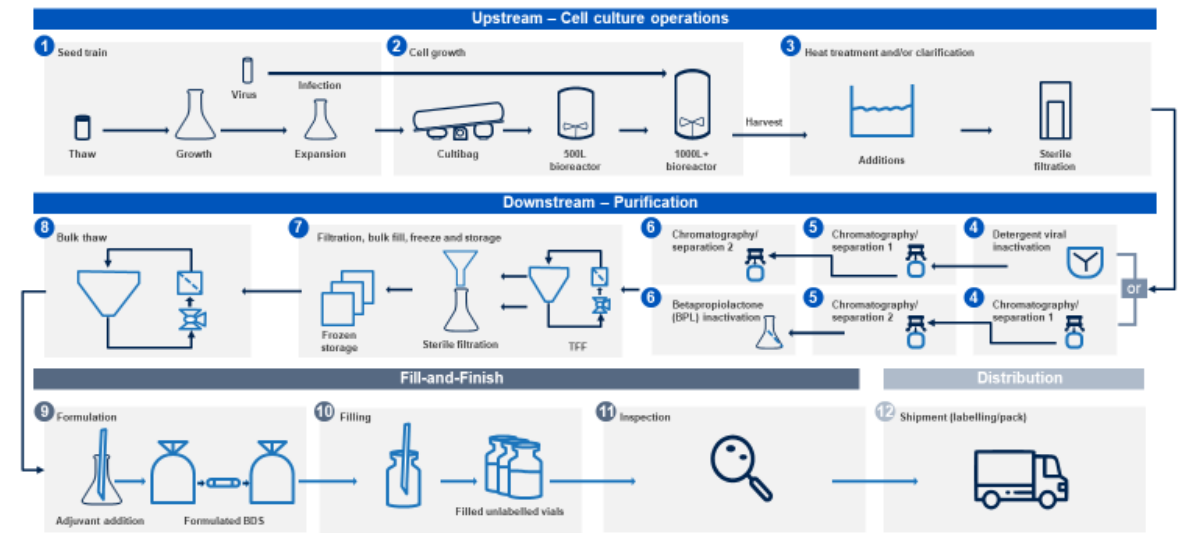
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1 Annex 1 – Vaccine Manufacturing Process By Technology Platform



Inactivated virus-based vaccines manufacturing process

■ Drug substance manufacturing ■ Fill-and-finish ■ Distribution



Source: Expert interviews, plant walkthroughs
DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE.
REFERENCES TO SPECIFIC ORGANISATIONS ARE SOLELY FOR INFORMATIONAL PURPOSES AND DO NOT CONSTITUTE ANY ENDORSEMENT OR RECOMMENDATION

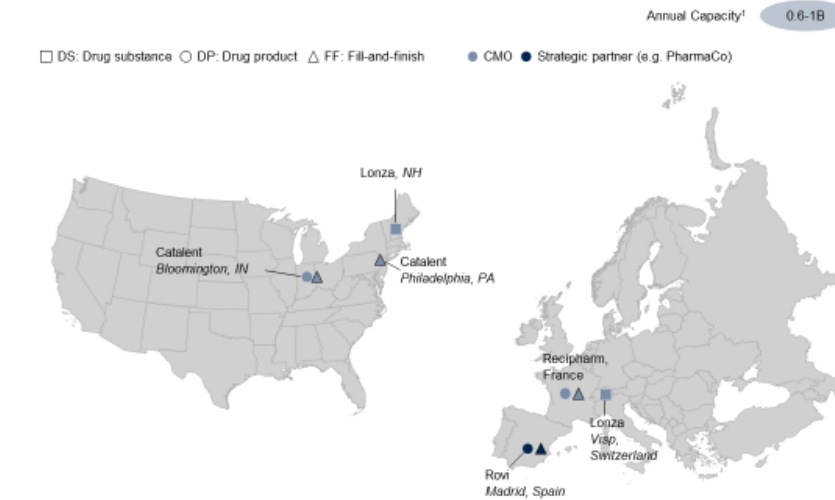
2 Annex 2 – Global COVID-19 Vaccine Manufacturing Networks

Known Vaccine Manufacturing Capacity – Moderna

CURRENT AS OF JANUARY 28, 2021

NON-EXHAUSTIVE

EXAMPLES FOR ILLUSTRATION PURPOSES ONLY



Annualised Capacity by YE 2021

Partner	Location	Capacity	New or existing
Lonza	Visp, Switzerland	300M	Refit/repurposed
Lonza	NH, USA	100M	Refit/repurposed
Catalent	Bloomington, IN, USA; Philadelphia, PA, USA (packaging and labeling)	100M	Refit/repurposed Philadelphia, PA is Existing
Rovi	Madrid, Spain	Hundreds of millions	Refit/repurposed
Recipharm	Monts, France	Not disclosed	Refit/repurposed

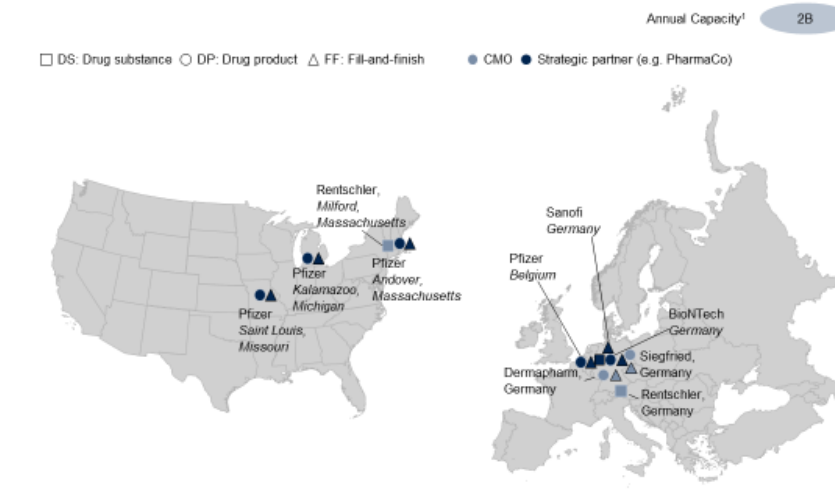
1 For COVID-19 vaccine production, no other mRNA vaccines are currently commercially available
Source: Bio Process Int'l, Moderna, Paul Ehrlich Institute, France Pharma
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Known Vaccine Manufacturing Capacity – BioNTech/Pfizer

CURRENT AS OF JANUARY 28, 2021

NON-EXHAUSTIVE

EXAMPLES FOR ILLUSTRATION PURPOSES ONLY



Annualised Capacity by YE 2021

Partner	Location	Capacity	New or existing
Pfizer	Saint Louis, MO, USA; Andover, MA, USA; Kalamazoo, MI, USA;	1.3B	Refit/repurposed
BioNTech	Marburg, Germany	750m	New purchase
Sanofi	Frankfurt, Germany	125m	Refit/repurposed
Rentschler	Laupheim, Germany; Milford, MA, USA	Not disclosed	Refit/repurposed
Siegfried	Hameln, Germany	Not disclosed	Refit/repurposed
Dermapharm	Brehna, Germany	Not disclosed	Refit/repurposed
Polymun	Not disclosed	Not disclosed	Refit/repurposed

1 For COVID-19 vaccine production, no other mRNA vaccines are currently commercially available
Source: Bio Process Int'l, BioNTech, BioNTech Investors, Paul Ehrlich Institute, France Pharma
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Known Vaccine Manufacturing Capacity – J&J

Annual Capacity¹

1B

□ DS: Drug substance ○ DP: Drug product △ FF: Fill-and-finish ● CMO ● Strategic partner (e.g. PharmaCo)



Annualised Capacity by YE 2021

Partner	Location	Capacity	New or existing
Vibiotics	Cuxhaven, Germany	Many thousands of doses	Refit/repurposed
Biological E	Acorn, India	165M	Refit/repurposed
Emergent BioSolutions	Baltimore, MD, USA	Not disclosed	New plant
Aspen (Pharmaceutical)	Port Elizabeth, South Africa	300M	Refit/repurposed
Grand River Aseptic Manufacturing	Grand Rapids, MI, USA	Not disclosed	Existing
Catalent	Bloomington, IN, USA; Anagni, Italy	Not disclosed	Existing

¹ For COVID-19 vaccine production, no other mRNA vaccines are currently commercially available
 Source: Pharmadeals, Reuters, Fierce Pharma, FiercePharma, Aspen, Catalent
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Known Vaccine Manufacturing Capacity – AstraZeneca²

Annual Capacity¹

3.2B

□ DS: Drug substance ○ DP: Drug product △ FF: Fill-and-finish ● CMO ● Strategic partner (e.g. PharmaCo)



Annualised Capacity by YE 2021

Partner	Location	Capacity	New or existing
Scotland Symbios	Stirling, Scotland	Not disclosed	N/A
Serum Institute	India	1B	Refit/Repurposed
Biokangtai	China	200M	N/A
Siam Bioscience	Thailand	Not disclosed	N/A
R-Pharm	Moscow, Russia	Not disclosed	N/A
Fiocruz	Brazil	480M	N/A
CSL	Australia	30M	Existing
mAbxience	Argentina, Mexico	200M	N/A
Emergent BioSolutions	Baltimore, MD, USA	Hundreds of millions of doses	New
Cobra	Newcastle, UK	12M	N/A
Halix	Netherlands	Not disclosed	N/A
Oxford Biomedica	Oxford, UK	Not disclosed	Existing
Catalent	Harmans, MD, USA; Anagni, Italy	Not disclosed	Existing
Novasep	Senefelt, Belgium	Not disclosed	Existing
SK Bioscience	Andong, China	Not disclosed	N/A
Albany Molecular Research	Albuquerque, NM, USA	Millions of doses	N/A
Wockhardt	North Wales, UK	100M	N/A

¹ For COVID-19 vaccine production, no other mRNA vaccines are currently commercially available
² Reported agreements with 20 contract manufacturing organisations in July 30, 200 H1 earnings call
 Source: Pharmadeals, Catalent, Symbios Pharma, Scip, Fiocruz, Biopharm, Novasep, FiercePharma, mAbxience, Halix, OJB, AMRI, Reuters, Fierce Pharma
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Known Vaccine Manufacturing Capacity – Novavax

CURRENT AS OF JANUARY 28, 2021

NON-EXHAUSTIVE

EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Annual Capacity¹ 2.1B

□ DS: Drug substance ○ DP: Drug product △ FF: Fill-and-finish ● CMO ● Strategic partner (e.g. PharmaCo)

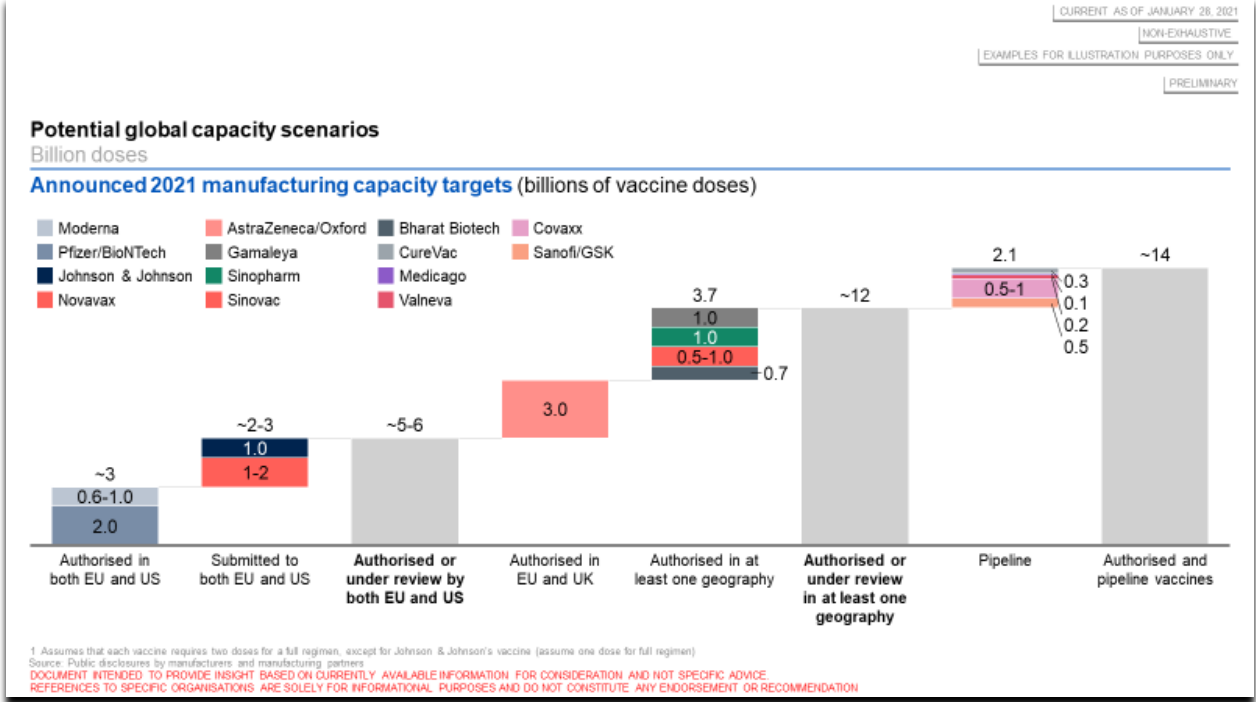


Annualised Capacity by YE 2021

Partner	Location	Capacity	New or existing
Takeda	Japan	250M	Refit/ repurposed
Serum Institute of India	Pune, India	1B	Refit/ repurposed
FUJIFILM	Morrisville, NC, USA; Texas, USA; UK	US: 100M UK: 180M	Existing
SK Bioscience	Andong L-house, South Korea	Not disclosed	N/A
Biofabri	Spain	Not disclosed	N/A
PolyPeptide Group	US; Sweden	Not disclosed	N/A
AGC Biologics	Denmark; Seattle, USA	Not disclosed	N/A
Endo International	Rochester, NY, USA	Not disclosed	N/A

¹ For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available
 Source: Pharmadeals, Catalent, Symbios Pharma, Scip, Ficuz, Biopharm, Novasep, FiercePharma, mAbsence, Halix, OXB, AMRI, Reuter, FiercePharma
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3 Annex 3 – COVID-19 Vaccine Supply Capacity by manufacturer

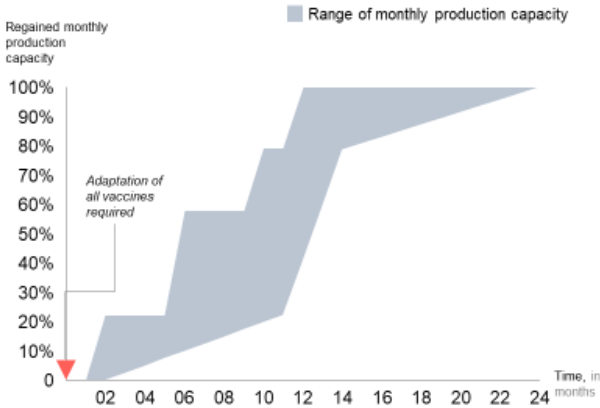


4 Annex 4 – Potential Ranges Of Capacity Ramp-Up Considering Variants

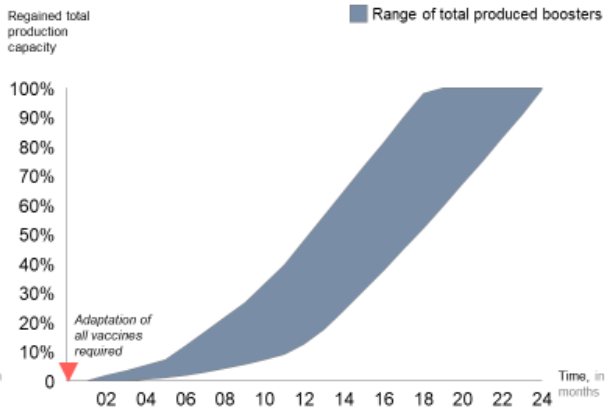
PRELIMINARY
AS OF 2021-02-10

Ramp-up of monthly vaccine booster supply and total production capacity in the first 2 years

Time to reach monthly baseline capacity of 1.2 billion doses, %



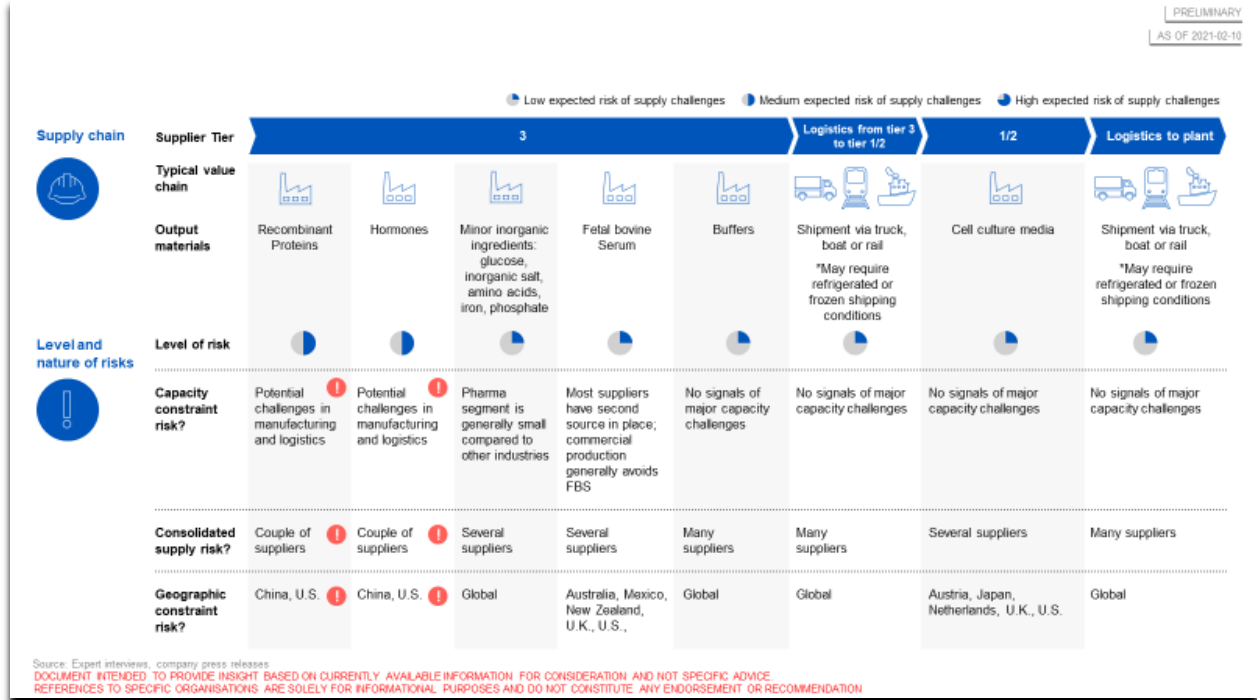
Time to reach annual baseline capacity of 14 billion doses, %



Depicted scenario is based on current vaccine portfolio (authorised for emergency use and late stage candidates with allocated supply). It assumes all other parameters remain constant and does not consider possible repurposing of manufacturing capacity from one vaccine to another. It assumes all technology platforms can be adapted to relevant variant(s), with different assumptions on speed for each platform













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5 Annex 5 – Overview of Potential Gaps in the Value Chain of Cell Culture Media Manufacturing



6 Annex 6 – Overview of Potential Gaps in the Value Chain of Lipid Nanoparticles Manufacturing

● Low expected risk of supply challenges
 ● Medium expected risk of supply challenges
 ● High expected risk of supply challenges

Supply chain		Upstream manufacturing of key components				Proprietary lipid blend for LNPs
		Supplier Tier	Supplier Tier	Supplier Tier	Supplier Tier	Supplier Tier
	Typical value chain					
	Output materials	Excipients, surfactants and preservatives	Cationic and pegylated lipid	Non-animal-based cholesterol	Ethanol	Ethanol, cholesterol, RNA, cationic lipids, PEGylated lipids, excipients, surfactants and preservatives
	Level of risk					
	Capacity constraint risk?	No signals of major capacity challenges	Current suppliers are scaling up	Refining/purification capacity potentially constrained !	No signals of major capacity challenges, and capacity is readily fungible	Supply of ethanol and non-animal-based cholesterol may be constrained !
	Consolidated supply risk?	Many suppliers	1-2 suppliers for cGMP lipids at scale !	1-2 suppliers for cGMP cholesterol at scale	Many suppliers	Generally formulated by mRNA vaccine manufacturer
	Geographic constraint risk?	Global	U.S., Europe	U.S.	Global	U.S., Europe

Source: Expert interviews, company press releases
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7 Annex 7 – Overview of Potential Gaps in the Value Chain of Glass Vial Manufacturing

