

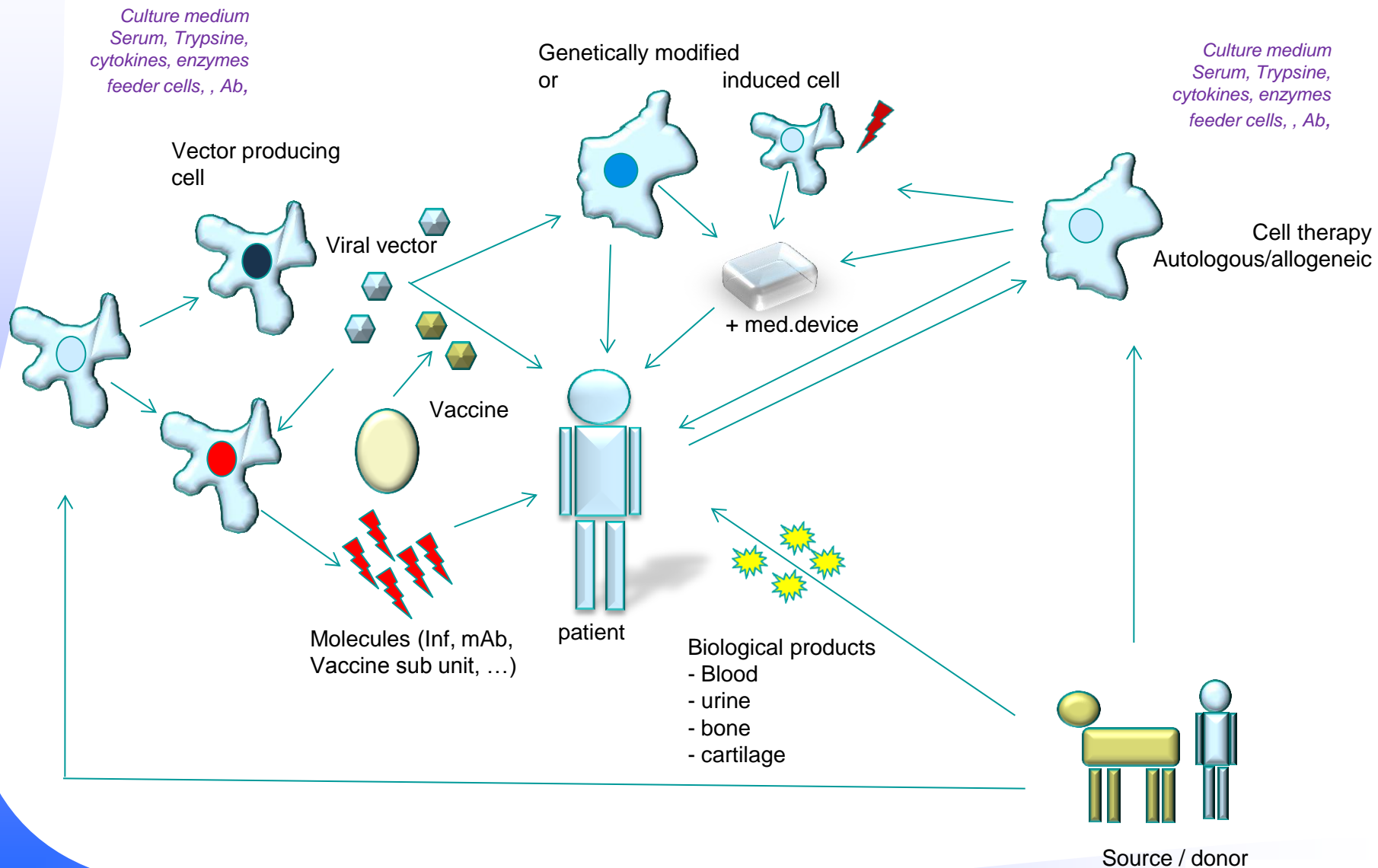


# *Sécurité virale des médicaments d'origine biologique*

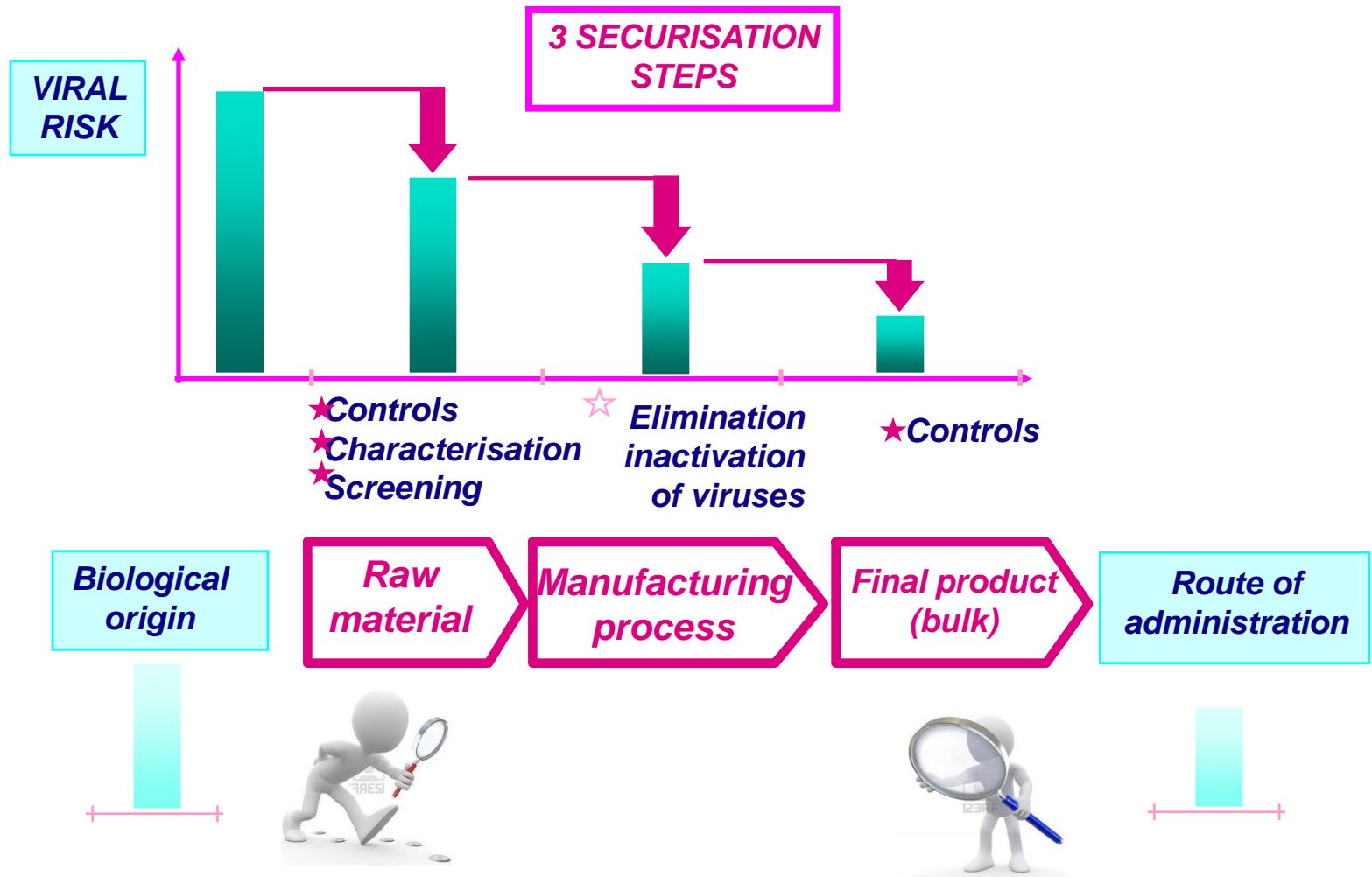


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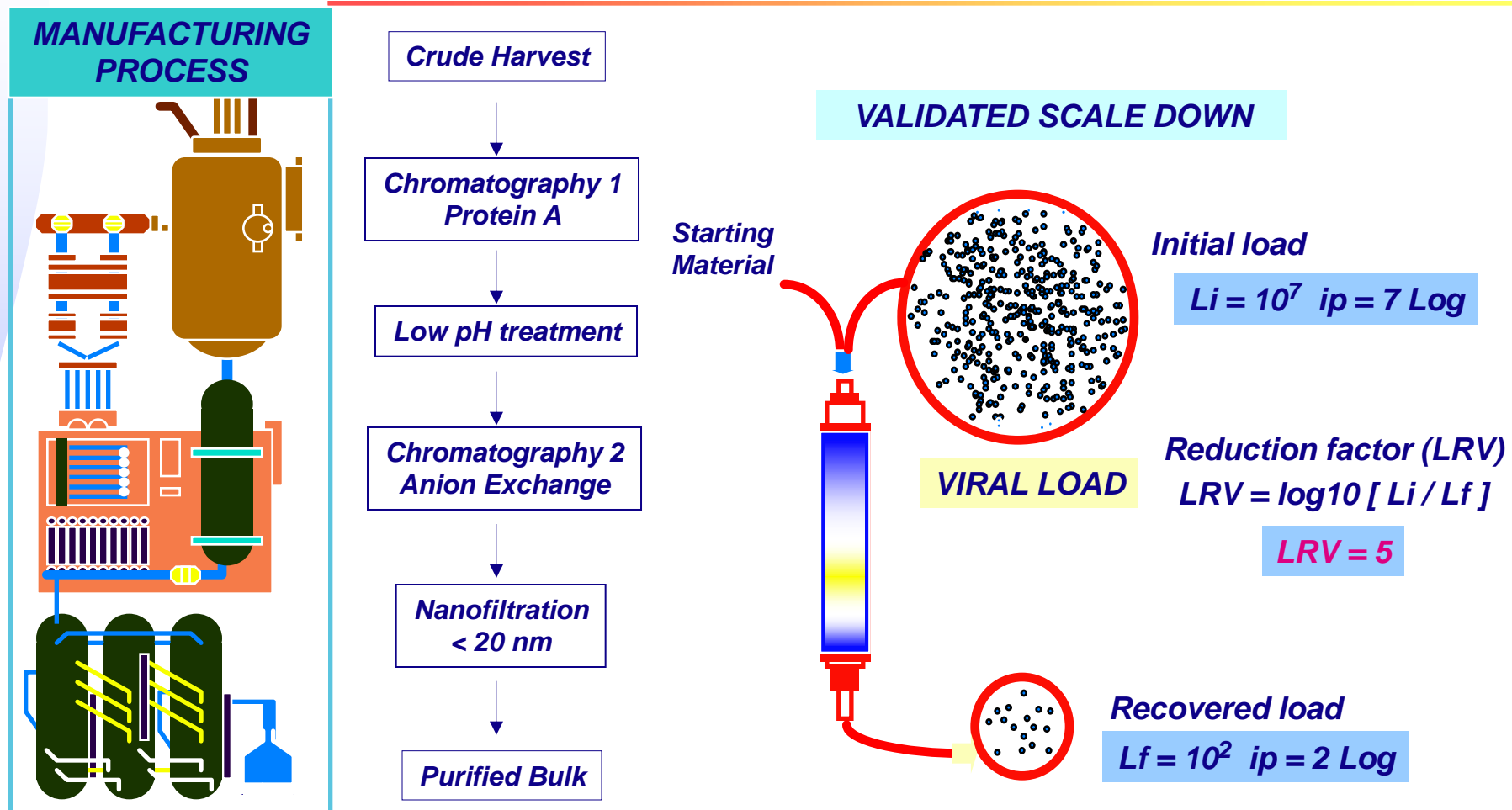
# Potential sources of contaminations



Source / donor

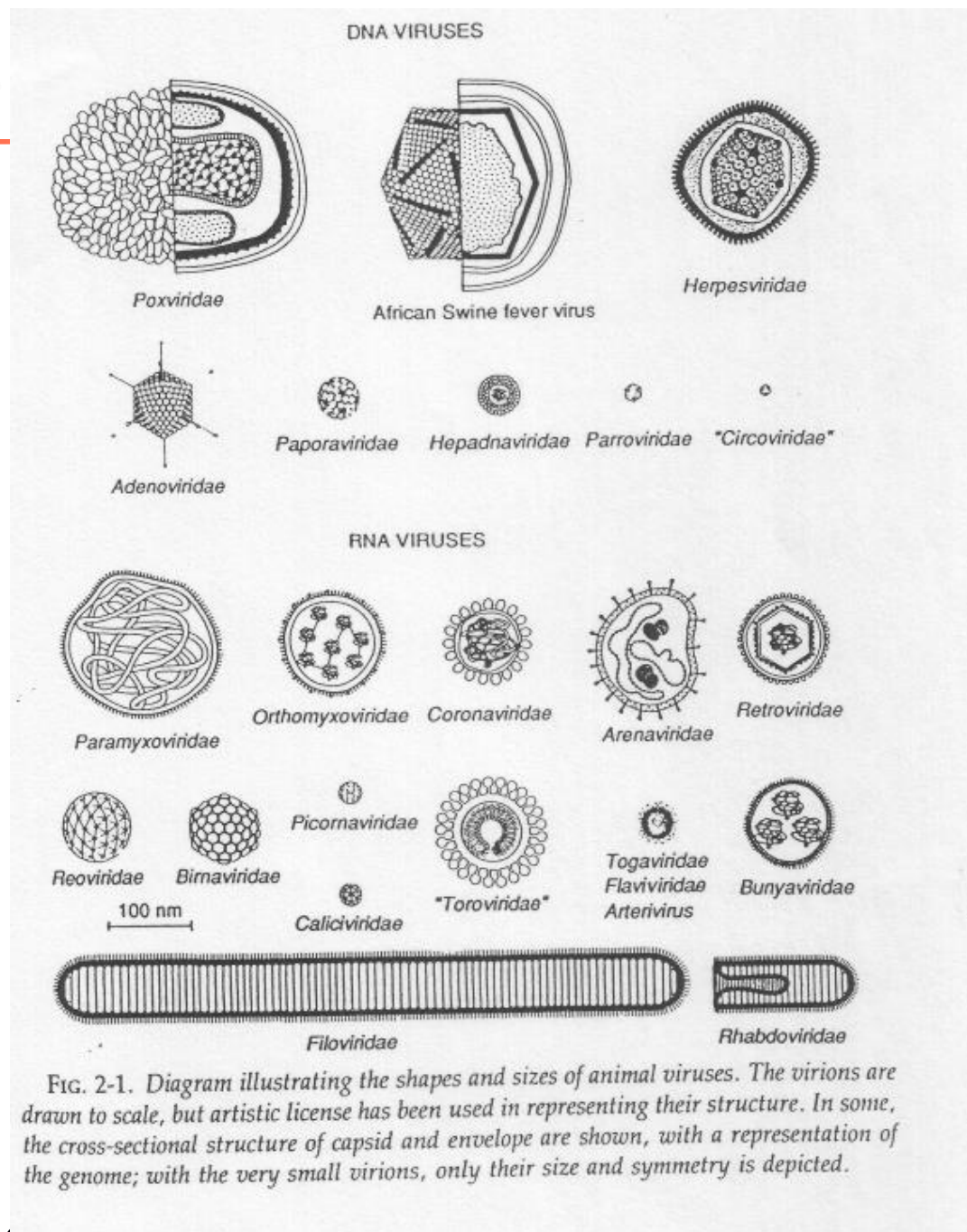


# Spiking experiment: LRV Definition



# Various aspects

- Size
- Env/non-env
- Viral titer
- Purification



- Excess capacity for viral clearance
- Quantification of virus present (infect, TEM, ...)
- Estimation of # virus / dose

$10^{E6}$  pfu / ml

1 dose = 1/

Load/dose =  $10^9$  pfu

$LRV > 15$

$$\text{VIRUS / DOSE} \Rightarrow \frac{10^9}{>10^{15}} \rightarrow < 1 \text{ pfu per } 10^6 \text{ doses}$$

# ***Viral clearance evaluation : key factors***

- ***Validated scale down***
- ***Clearance excess: elimination of more virus than potentially present in one patient dose equivalent of Un P Bulk.***
- ***Different mechanisms of clearance : no repeat of identical procedures***
- ***In case one step change, all steps downstream need to be re-validated***





# ***Thank you ! Any questions ?***

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