



美迪西微信公众号

一站式临床前医药研发服务平台

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上海美迪西生物医药股份有限公司
SHANGHAI MEDICILON INC.

2004 CRO()

2019 11 5 CRO

688202



先进的实验设施和资质

-
-
- AAALAC
- NMPA GLP
- FDA GLP



专业稳定的研发团队

-
- 10
- 80%
- 30%



完善便捷的服务体系

-
-



丰富的实战案例及申报经验

-
- 2015 421个
- NMPA/ FDA/ TGA/ EMA



获得政府关怀及认可

- 9
- 4
- “ ” “ ” “ ” “ ” “ ”



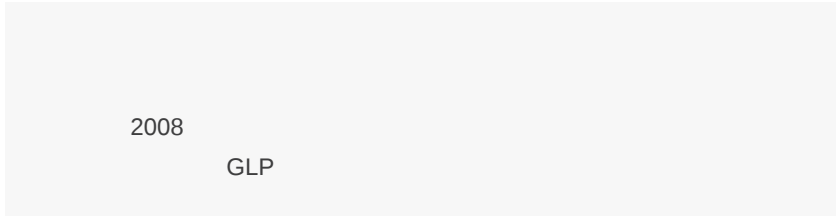
严格的知识产权保护政策

-
-



2004 -2008

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- 2



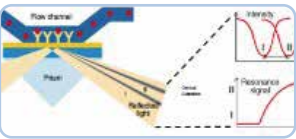
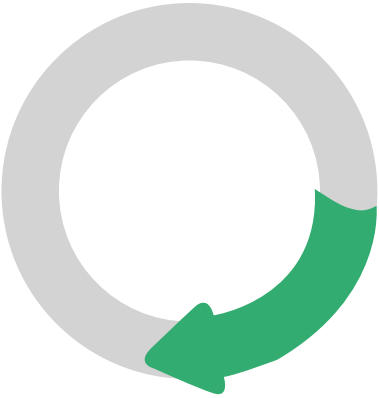
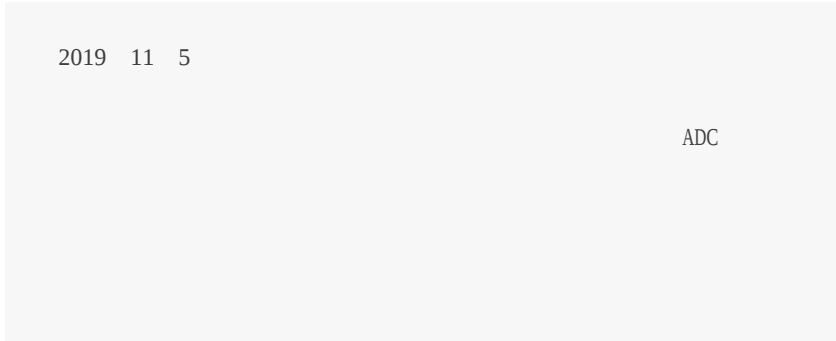
2009 -2014

- ()
- GLP
- AAALAC
-

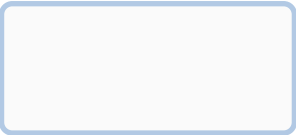


2015 -

- FDA GLP
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Biacore



PROTAC

RNAi CAR-T

新药
研发
流程

美迪西
一站式
服务

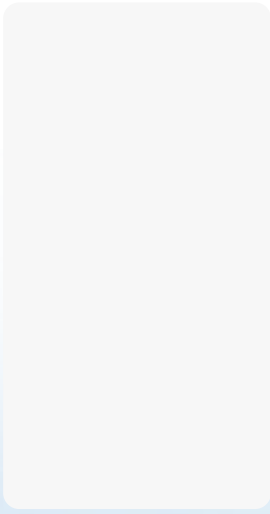
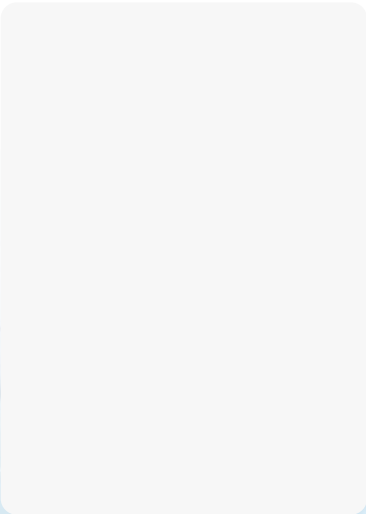
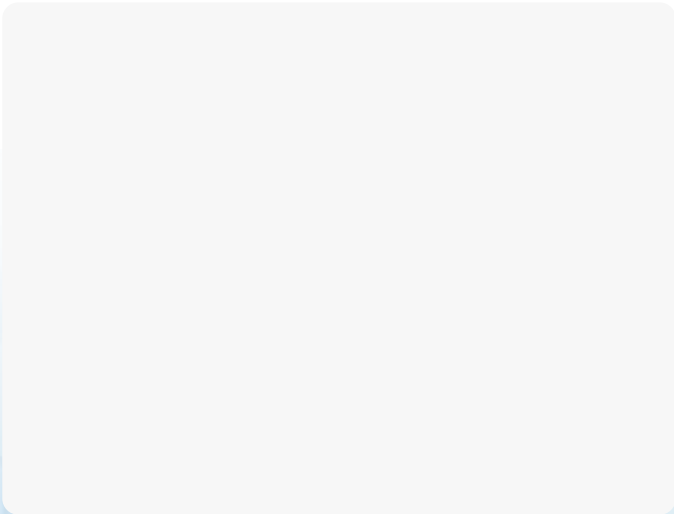


药物发现

药学研究

临床前研究

IND申报

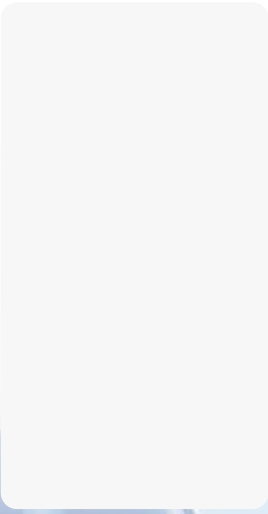


DMPK

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-
-

ADME

- P450
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-

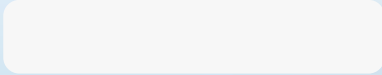
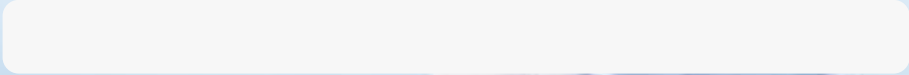
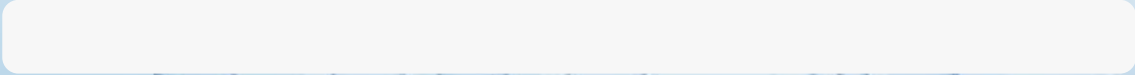


NMPA

US FDA

TGA

EMA





GMP

CRO CDMO



01

5-10

/

02

BE

API
100%

API

03

2 cGMP
BE

IND

04

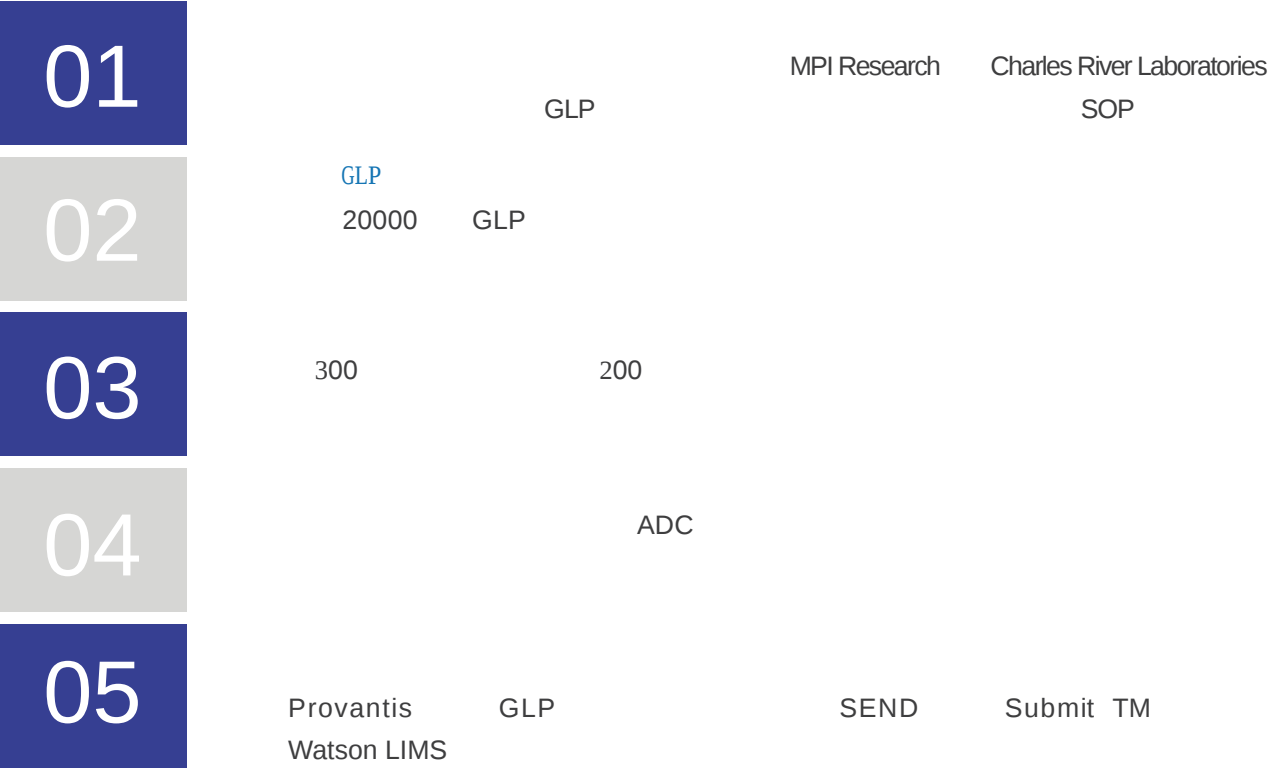
API



- API
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- API
-
- API
- DMF (QbD)
- API
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- 1 : /
- 2
- 3 4
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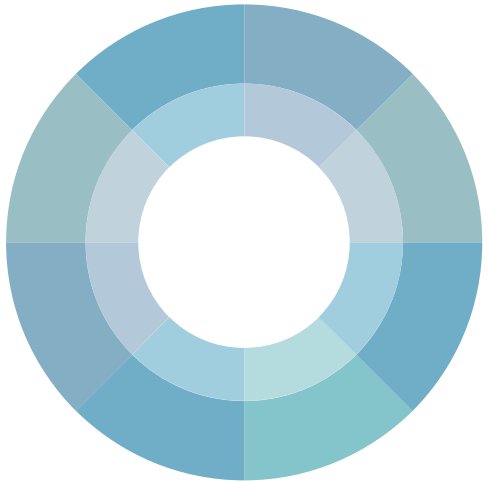


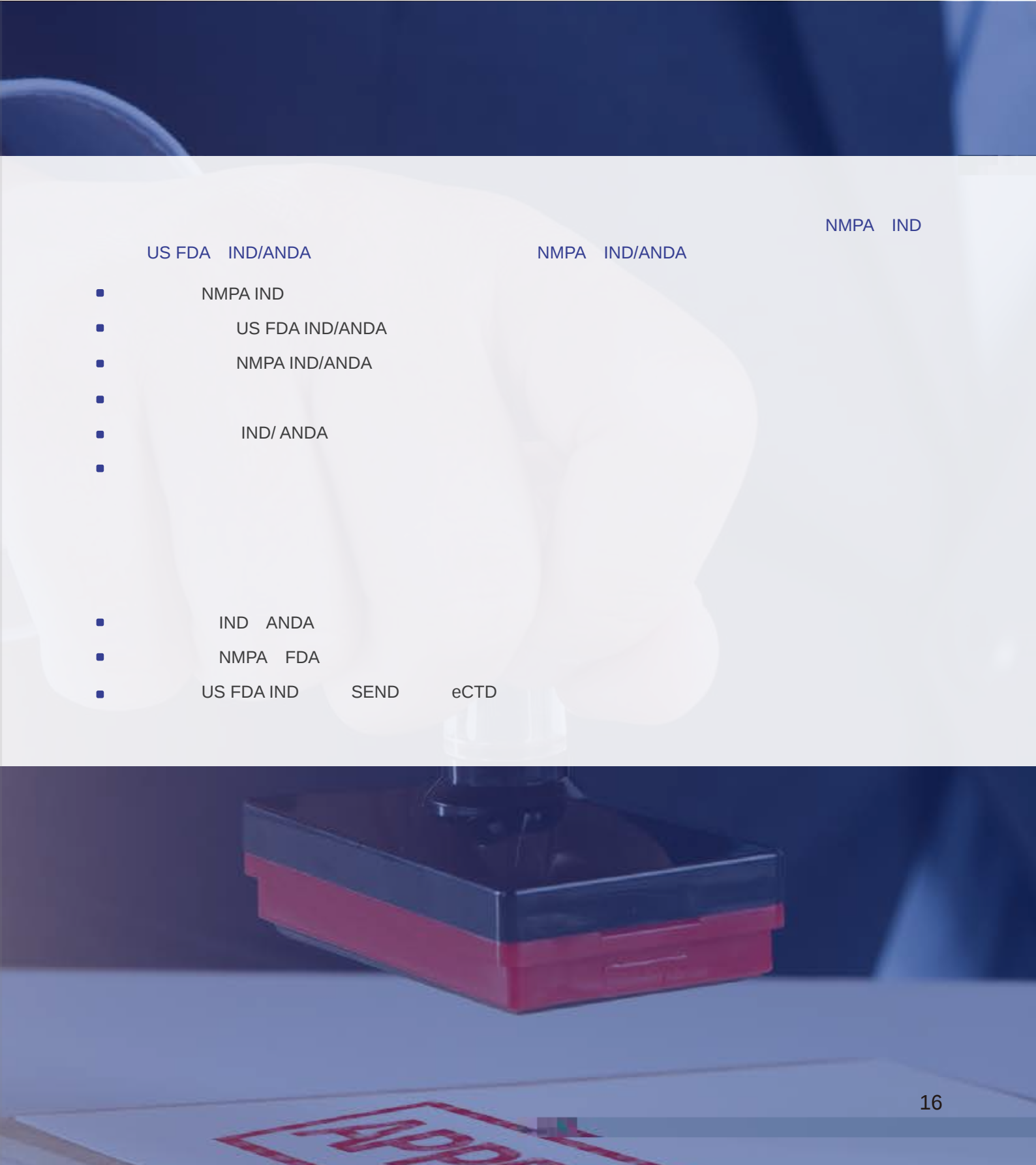
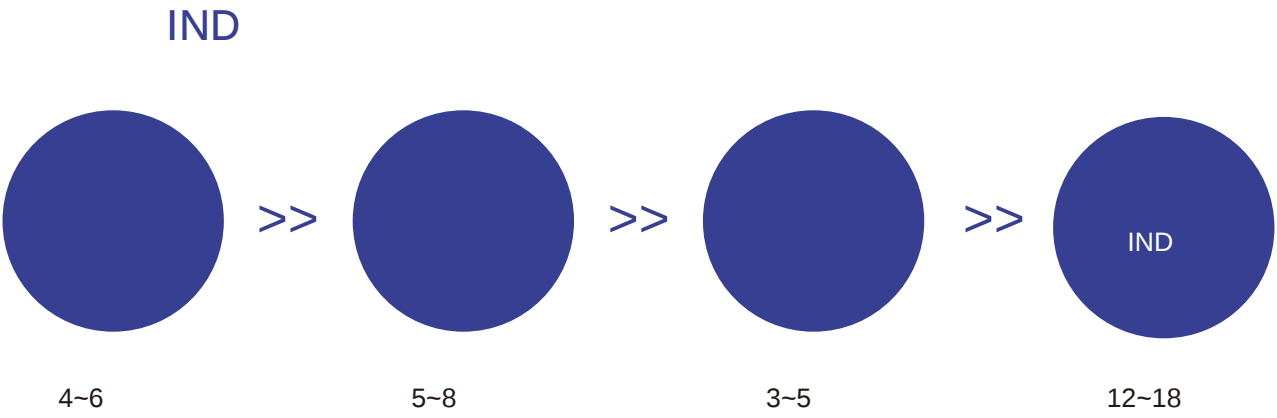
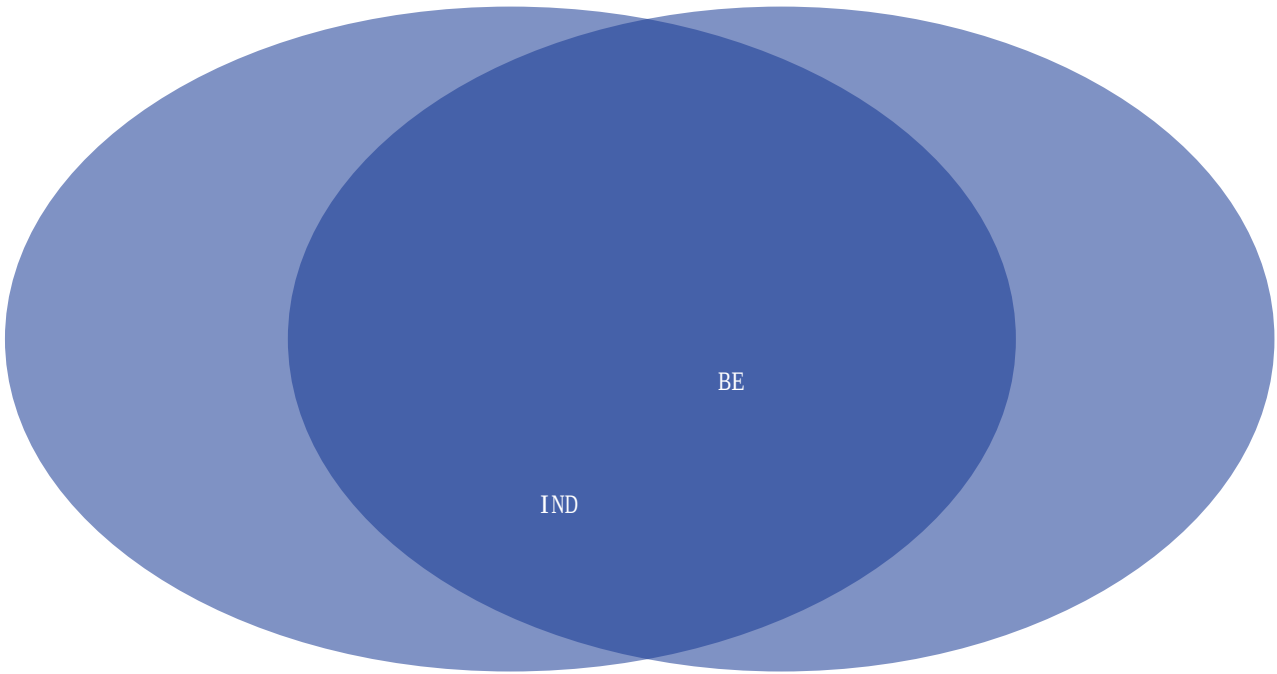


 AAALAC	 GLP	 GLP	 QA RQAP-GLP
			

~186 ~30 ~30 ~50 ~100 PDX Models	~64 ~32 ~25 ~18 ~39 ~52
★ IVIS PET-CT	Resource 20

GLP			
/	(含hERG测试)	- HE - IHC) - TCR)	





- US FDA IND/ANDA
- NMPA IND/ANDA
- NMPA IND
- NMPA IND
 - US FDA IND/ANDA
 - NMPA IND/ANDA
 -
 - IND/ ANDA
 -
-
- IND ANDA
 - NMPA FDA
 - US FDA IND SEND eCTD

