加强新药审批
PMDA's Efforts to strengthen New Drug Review
– 加快审批速度 –
- How we accelerate reviewing speed -

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Shanghai, China

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古代中国（三皇五帝的时代）
Ancient China

神农尝百草调查是毒还是药
Shennong used to judge the poison or the medicine by tasting various grasses.

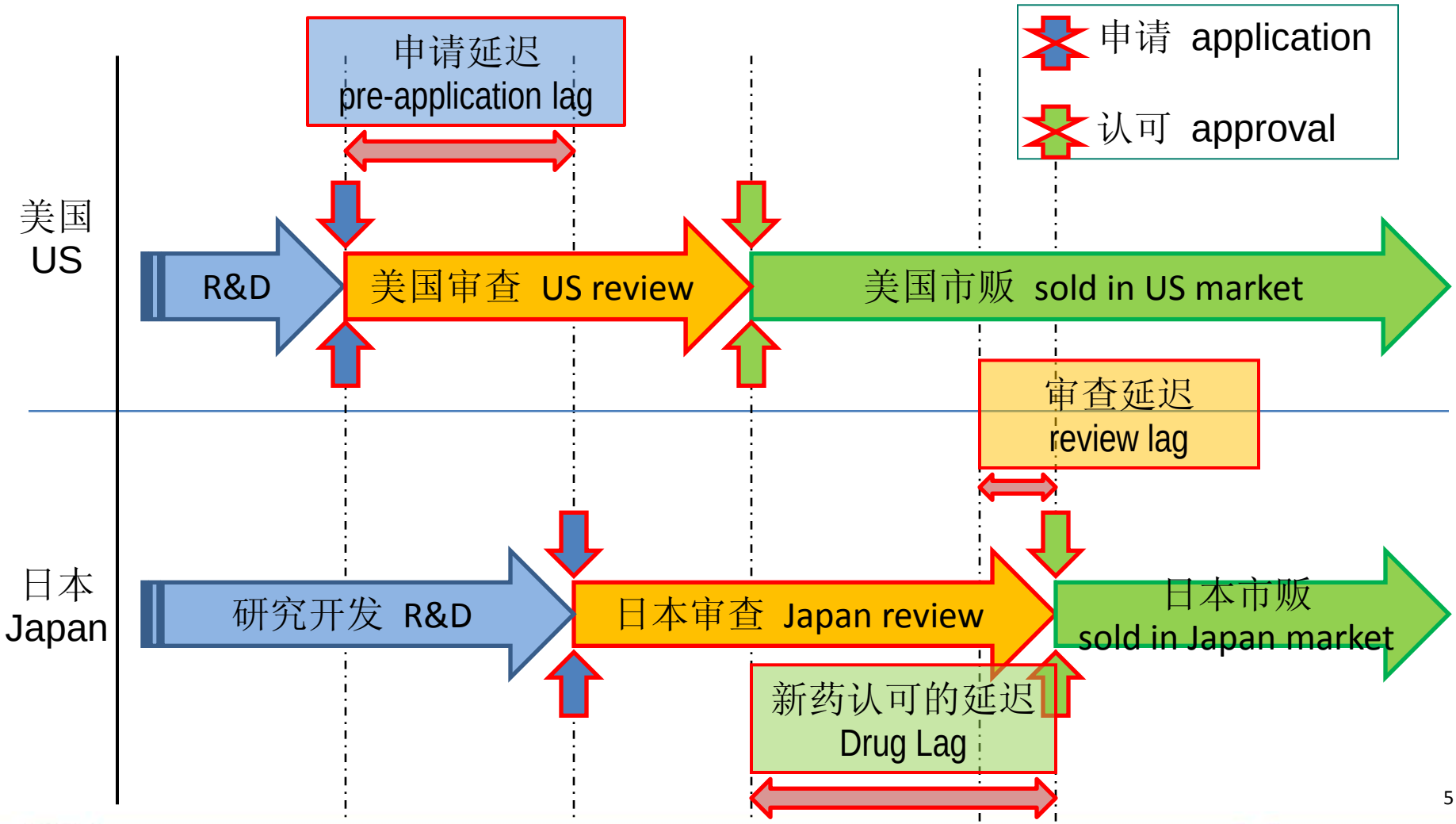
现代日本
Present Japan

PMDA审查医药的有效性调查安全性
PMDA examines the effectiveness of the medicine and investigates safety.

What is Drug Lag?

新药认可的延迟 是什么？

3个延迟 Three types of lag



用语的定义 definition of term

申请延迟
pre-application lag

与在美国的申请时期的差的中位数
The median of the difference of application time between Japan and the U.S.

+

审查延迟
review lag

日美间的新药的总审查期间(中位数)的差
The difference of the total review period (median) of the new drug between Japan and the U.S.

=

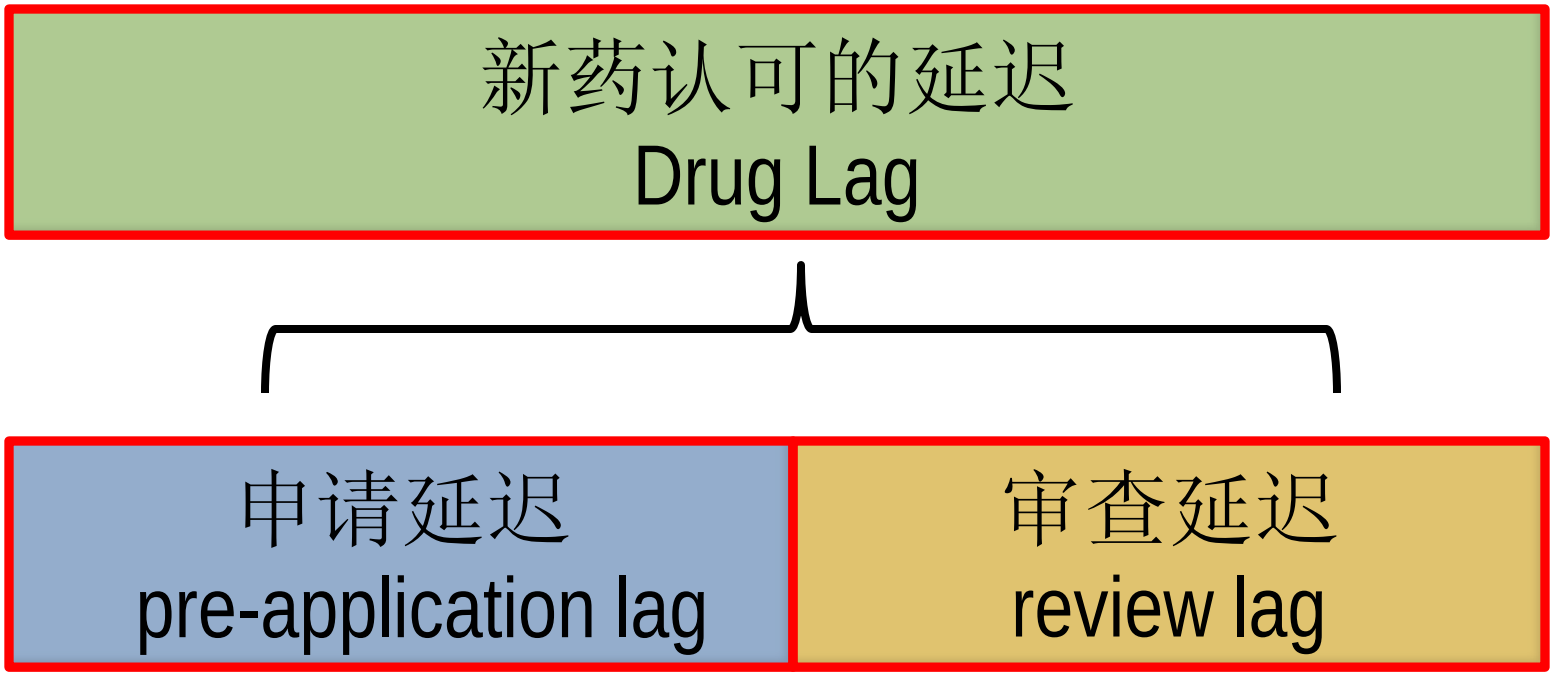
新药认可的延迟
Drug Lag

申请延迟和审查延迟的共计
The sum of pre-application lag and review lag.

How can we shorten Drug Lag?

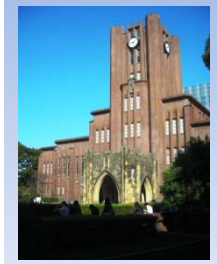
怎样做能缩短新药认可的延迟？

3个延迟的关系
The relation of three lag



如何是不是缩短申请延迟？
How can we shorten pre-application lag ?

研究者Researcher:大学和研究机关等 university, research institution, etc.



用基础研究发现新成分

New ingredients are discovered by basic research.

可是连接到新药开发的资金和手段都没有

However, they have no funds and means to develop new drug.

相隔 GAP

开发者Developer:制药企业 drug manufacture company

用新成分进行新药开发

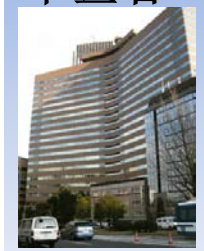
New drugs are developed using new ingredients.

为了申请　需要完全准备资料

In order to apply, it is necessary to prepare data completely.

相隔 GAP

审查者Reviewer:医药品及医疗器械管理机构 PMDA



根据申请　资料进行新药审查

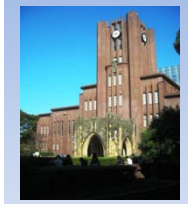
New drugs are reviewed only based on their application data.

不完全的资料查询花费时间

Imperfect data require time for reference.

研究人员方面和开发者方面
Researcher side and Developer side

研究者Researcher:大学和研究机关等 university, research institution, etc.



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药事战略咨询
Pharmaceutical Affairs Consultation on R & D Strategy

详细安藤先生说明的预定

Mr. Ando is going to explain for details.

开发者方面和审查者方面
Developer side and Reviewer side

临床试验咨询
Clinical Trial Consultation

详细高野先生说明的预定
Mr. Takano is going to explain for details.

开发者Developer:制药企业 drug manufacture company

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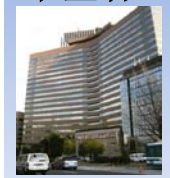

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如何是不是缩短审查延迟？
How can we shorten review lag ?

审查期间和工作量逆相关

Review time is inversely correlated with the output.

$$\text{审查期间 review time} \propto \frac{1}{\text{工作量 output}}$$

$$\text{工作量 output} = \text{职员的本领 staff skill} \times \text{职员的人数 staff size}$$

如何是不是缩短审查延迟？
How can we shorten review lag ?

职员的本领
staff skill

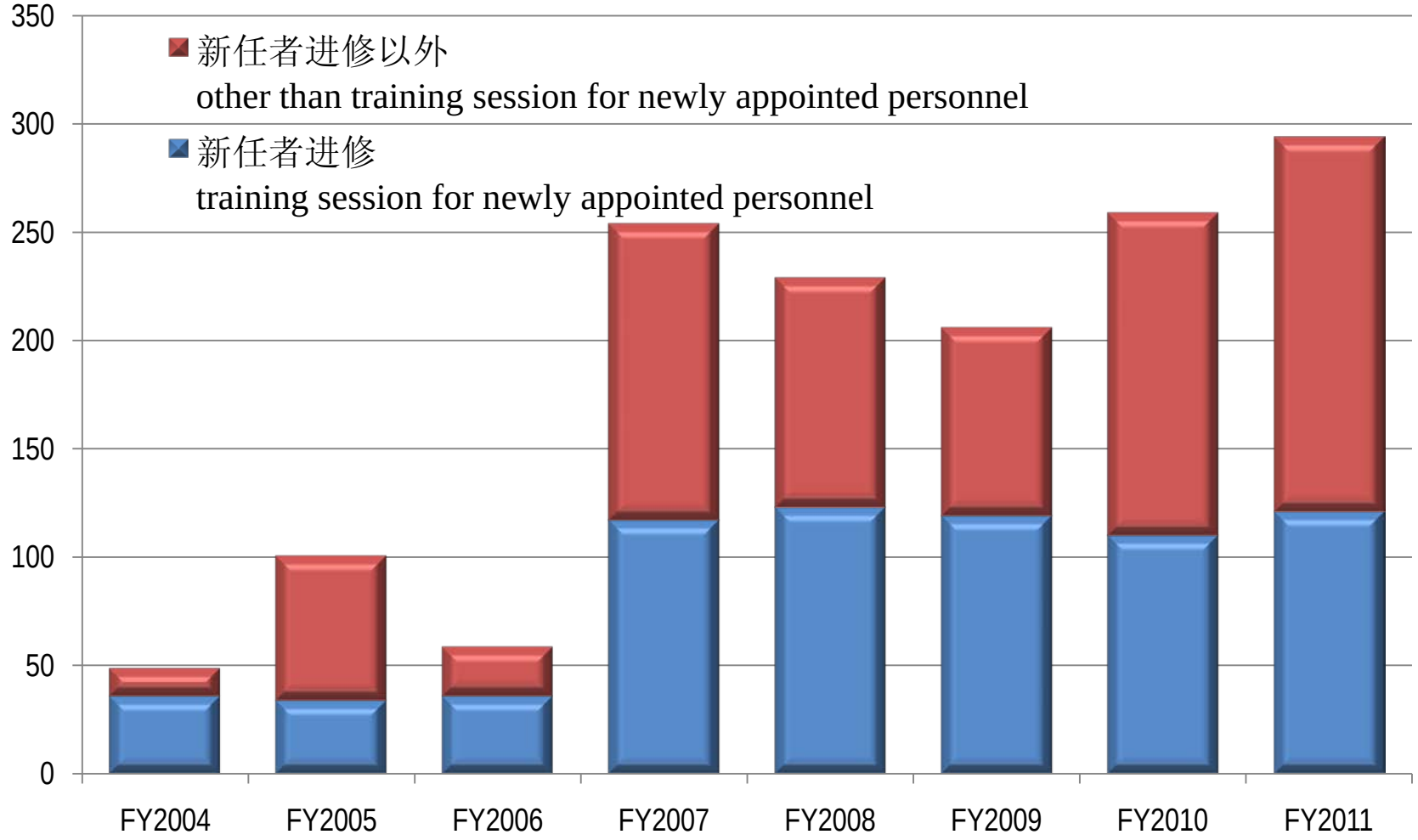
进修的充实 to enrich training

人材交流的促进
to promote talented-personnel exchange

职员的人数
staff size

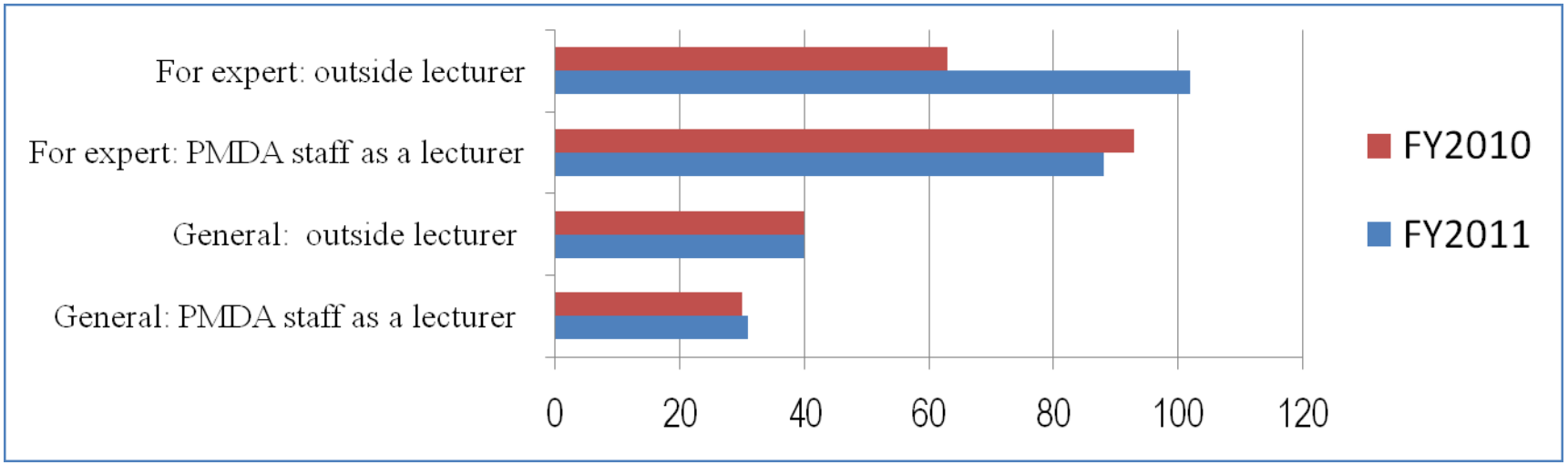
增加职员数
to increase number of personnel

进修的充实 -内部进修
to enrich training – internal trainings

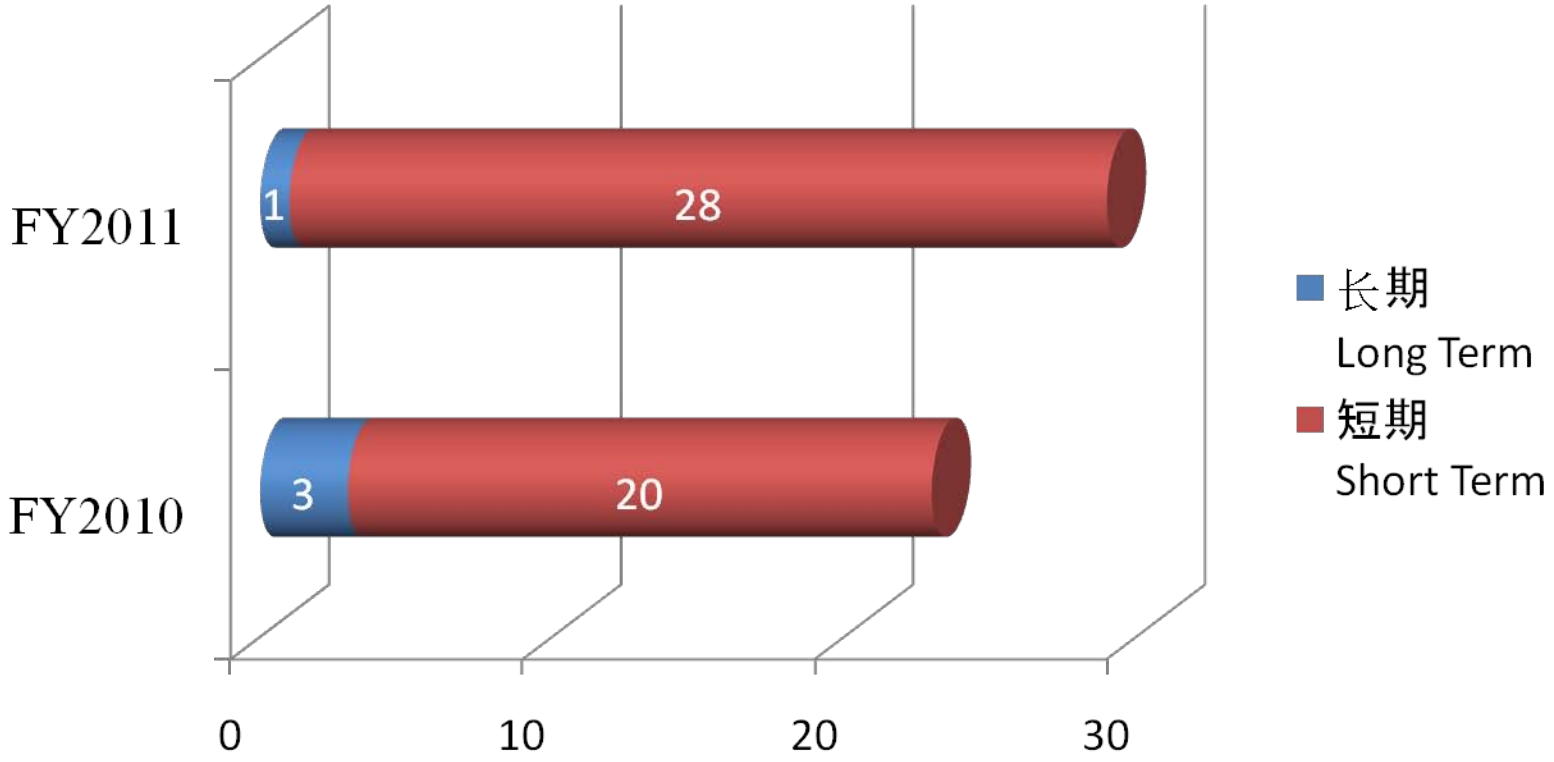


进修的充实 - 外部设施的访问进修
to enrich training - Observational Training at outside facilities

	FY2007	FY2008	FY2009	FY2010
外部设施的访问进修 Observational Training at outside facilities	21	16	10	13
参加职员数　Participants	249	219	187	229



进修的充实 - 海外进修参加者数
to enrich training - number of participants for overseas trainings



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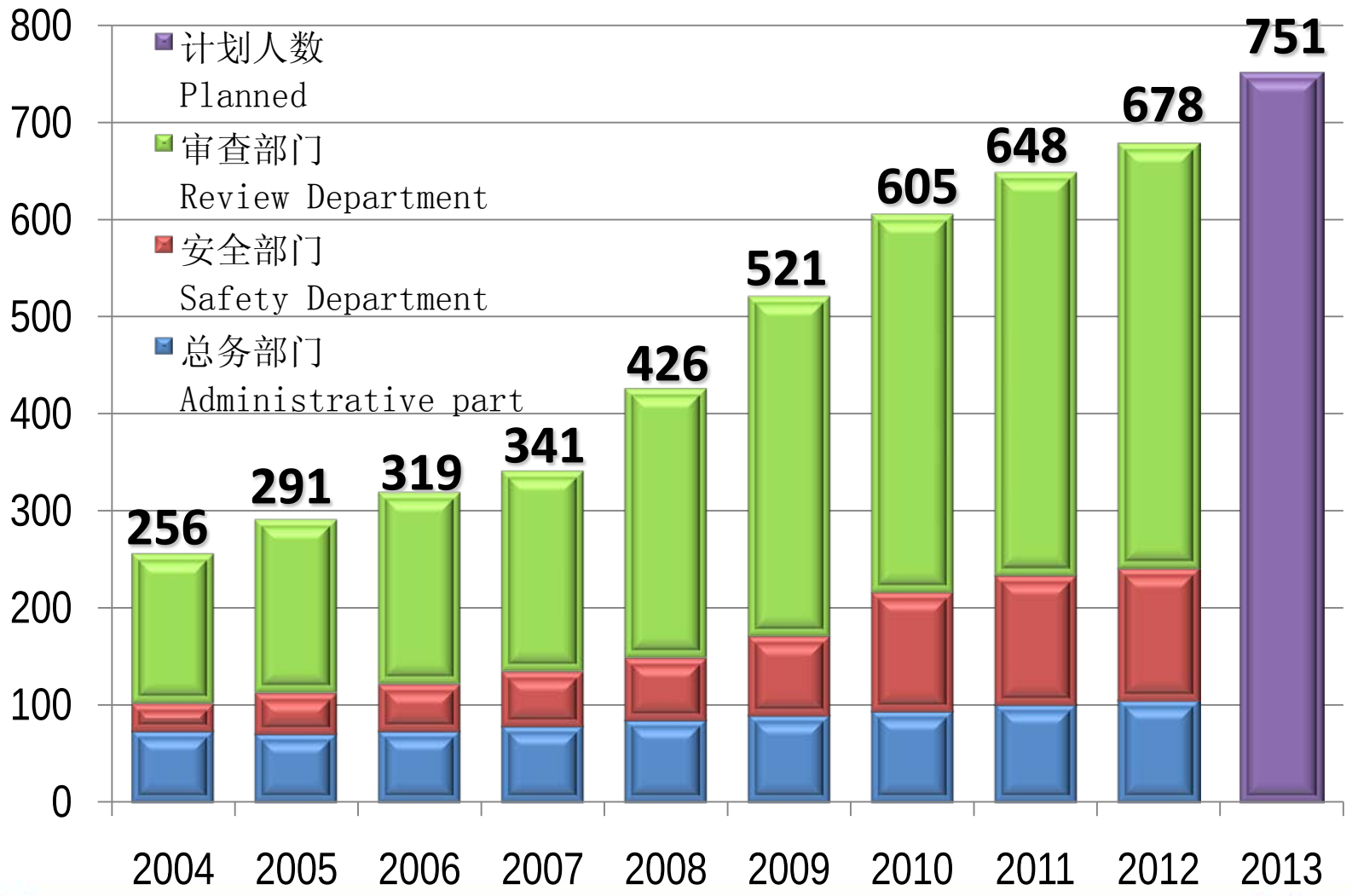
PMDA职员数　PMDA Staff Size



As the Result

作为结果

新药审查期间
Review Time for New Drugs

优先审查品种 Priority Review Products

	FY 2007	FY 2008	FY 2009	FY 2010	当初目标 FY2011 Target
总审查期间 Total Review Time (Month)	12.3	15.4	11.9	9.2	9
限制当局审查时间 Regulatory Review Time	4.9	7.3	3.6	4.9	6
申请者方面时间 Applicant's time	6.5	6.8	6.4	3.4	3

通常品种 Standard Review Products

	FY 2007	FY 2008	FY 2009	FY 2010	当初目标 FY 2011 Target
总审查期间 Total Review Time (Month)	20.7	22.0	19.2	14.7	12
限制当局审查时间 Regulatory Review Time	12.9	11.3	10.5	7.6	9
申请者方面时间 Applicant's time	7.9	7.4	6.7	6.4	3

新药认可的延迟 Drug Lag

	FY2007	FY2008	FY2009	FY2010
申请品种数 The number of applied items	89	76	97	116
申请延迟 pre-application lag	2.4yr	1.5yr	1.5yr	1.0yr
审查延迟 review lag	1.0yr	0.7yr	0.5yr	0.1yr
新药认可的延迟 drug lag	3.4yr	2.2yr	2.0yr	1.1yr


视听谢谢
Thank you for your attention