

# 干货|FDA的GMP检查

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U.S. Food and Drug Administration  
Protecting and Promoting Public Health

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## FDA的GMP检查

CDER

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1



## 概述

- 批准前检查 (Pre-Approval Inspection , PAI)
- 基于风险的GMP检查
  - 日常检查
  - 批准后检查
  - 检查趋势
- 产品召回

2



## 21世纪倡议的药品质量监管框架

### 指导原则:

- 强有力地保护公众健康
- 基于风险的定位
- 基于科学的政策和标准
- 整合质量体系目标
- 开展国际合作

3

## 理想状态：行业、社会以及监管部门的共同目标

制药行业达到最大限度高效、敏捷、灵活的状态，能够可靠地生产高质量的药品，而无需广泛监管。

——Janet Woodcock, M.D.

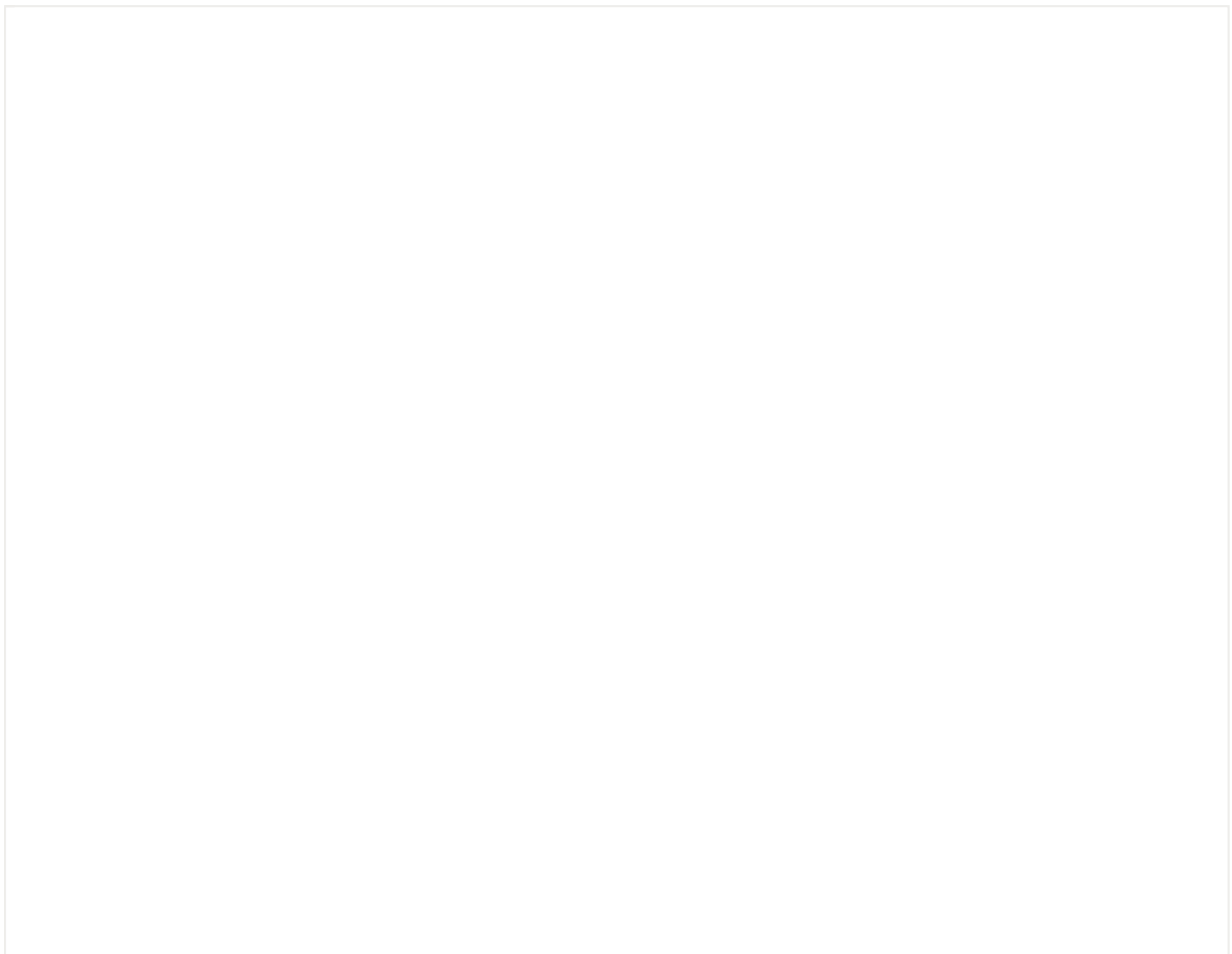
4

## 批准前检查计划

《联邦食品药品化妆品法案》规定，只有药品生产、加工、包装和检测所使用的方法，以及用于药品生产、加工、包装和检测的设施和控制措施足以确保药品的特性、规格、质量和纯度的情况下，FDA才能批准NDA或ANDA。

参见FD&CA法案第505(d)条、第505(j)(4)(A)条 (21 U.S.C. § § 355(d)(3)、355(j)(4)(A))

5



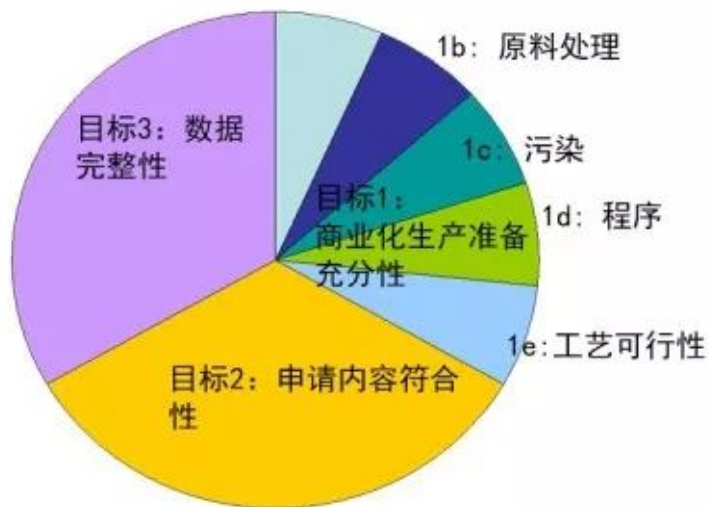
类别体系 (profile system) 以产品类别或级别为基础，而不是基于特定产品，特定类别对应具体类别分级代码，合适的类别分级可用于描述企业生产或加工的产品[1]。

**表 分级代码举例**

分级代码	定义	解释
CFN	Non-sterile API by fermentation	经发酵的无菌原料药
CFS	sterile API by fermentation	经发酵的非无菌原料药
CHG	Capsules, prompt release	迅速释放胶囊
CSG	Capsules, soft gelatin	软明胶胶囊
CTR	Capsules, modified release	缓释胶囊
TCM	Tablets, prompt release	迅速释放片剂
TTR	Tablets, extended release	缓释片剂



### 1a: 研究情况/趋势



## PAI目标 (Sections 3.3 – 3.4 CPGM)

9

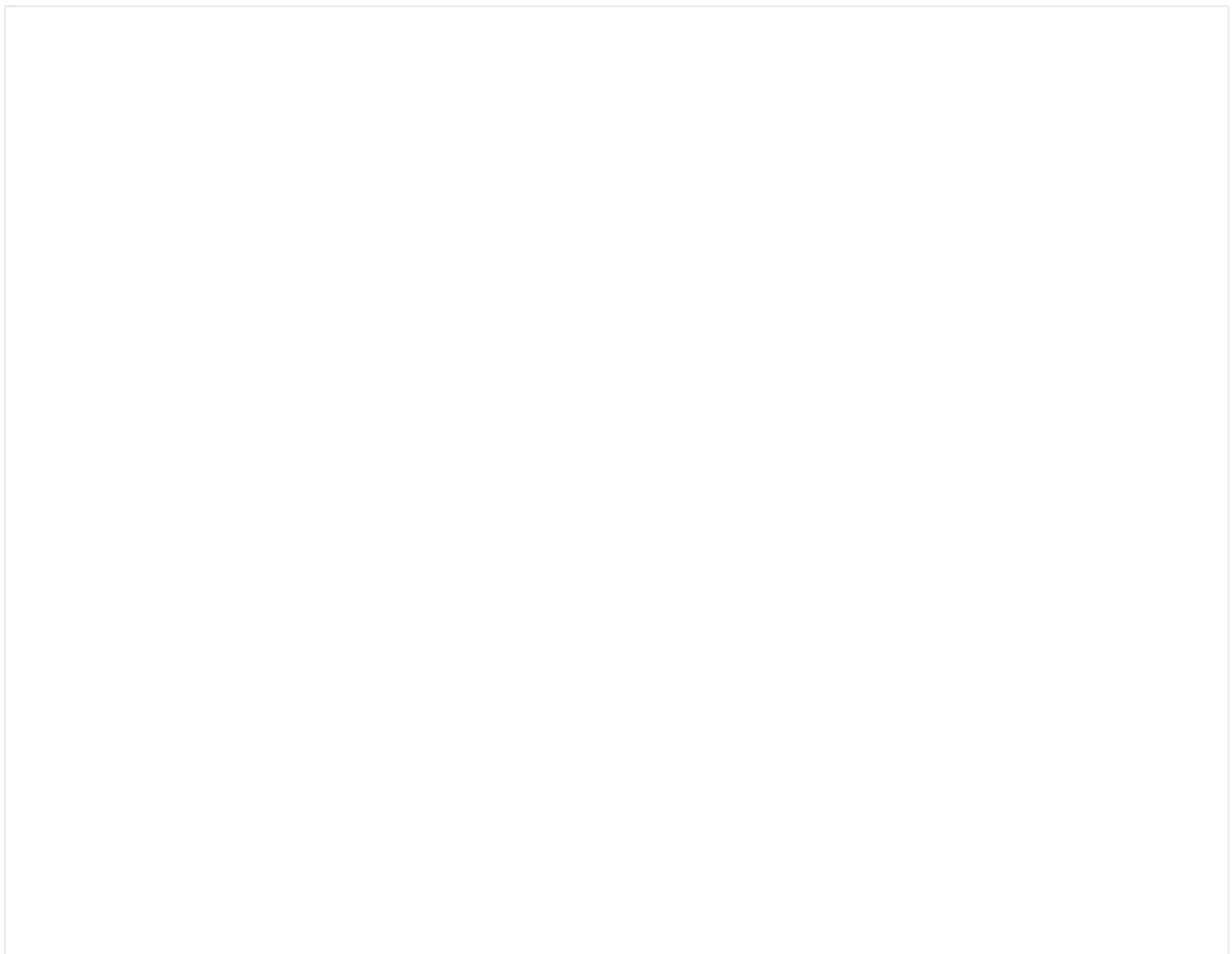


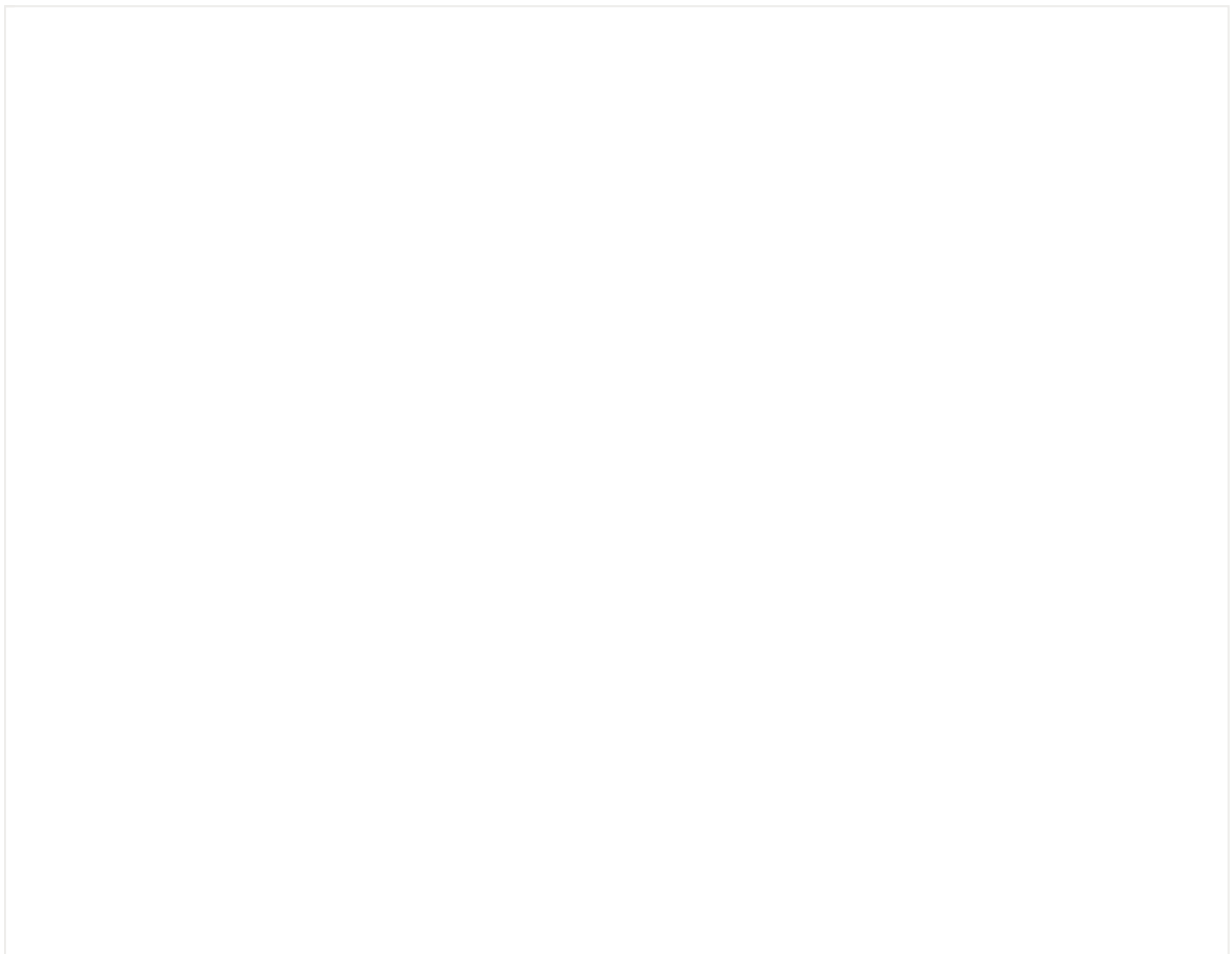
## PAI暂停建议 (withhold recommendation) 的主要原因

- 未决执法行动/之前的偏差仍然存在
- 企业未准备好接受检查/药品不在该生产场地生产/生产企业登记取消 (facility withdrawn)
- 研发数据/生产/工艺控制不充分
- 实验室控制不充分
- 质量保证职责不充分

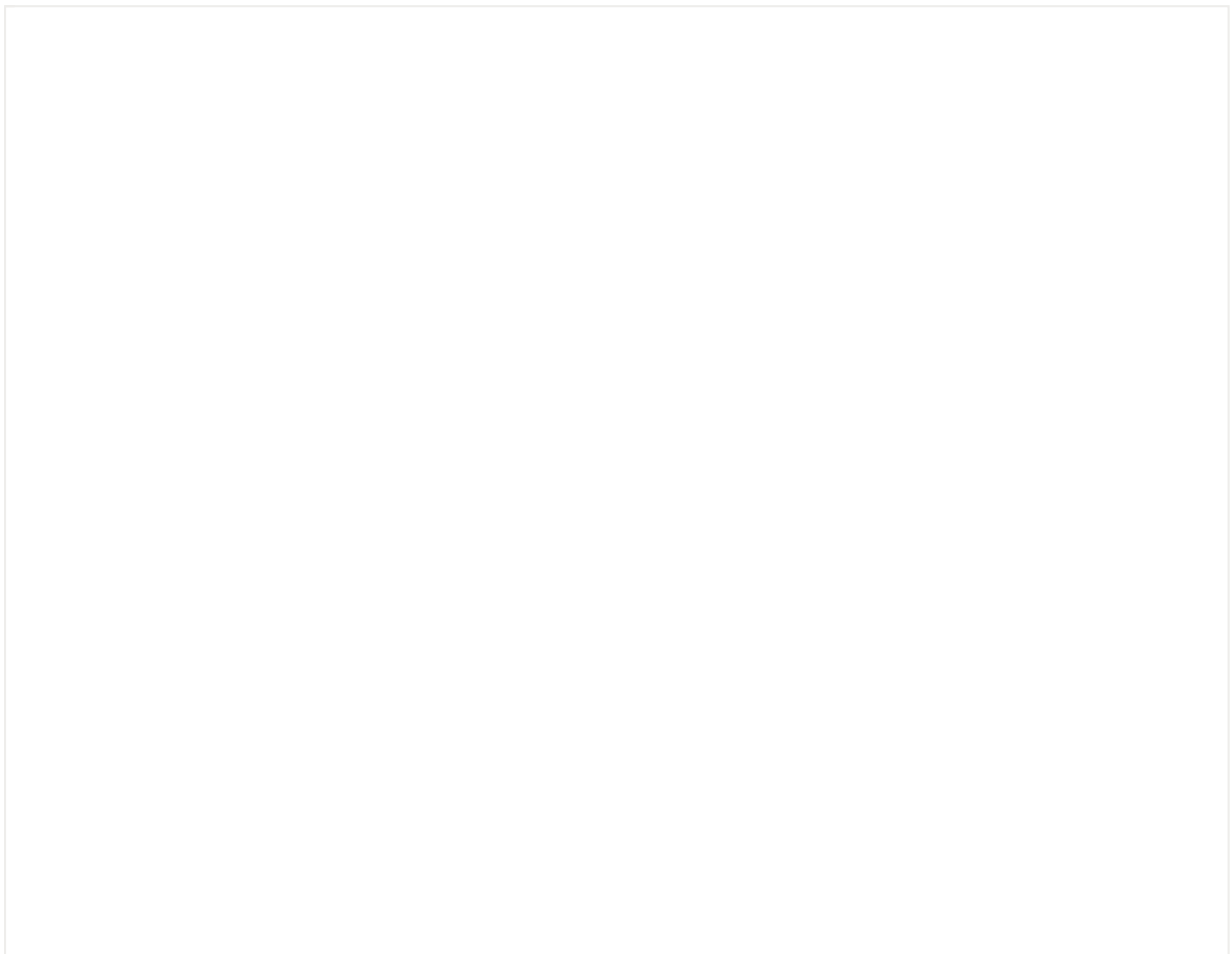
\*数据来源: 生产场地评估系统, 暂停建议

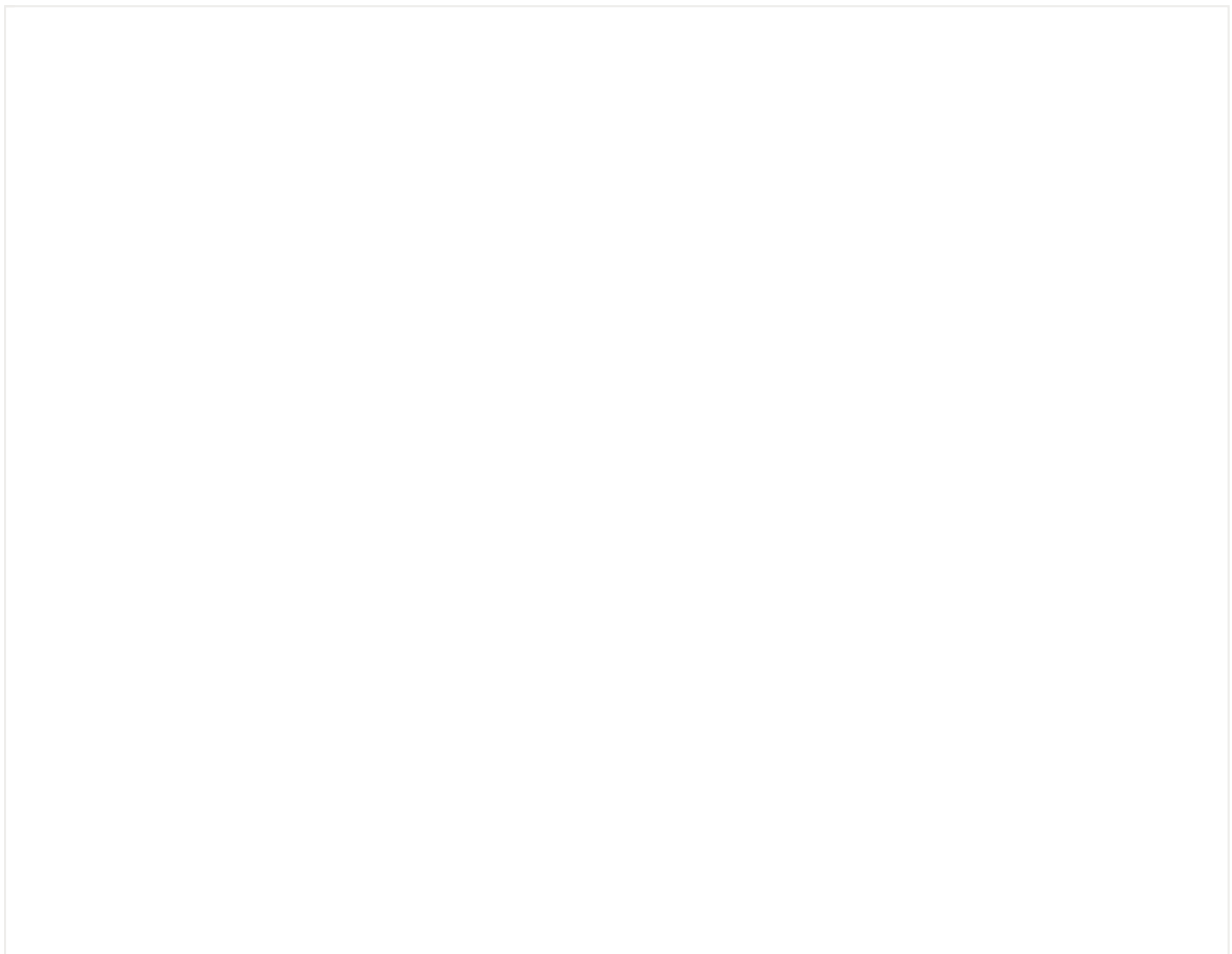
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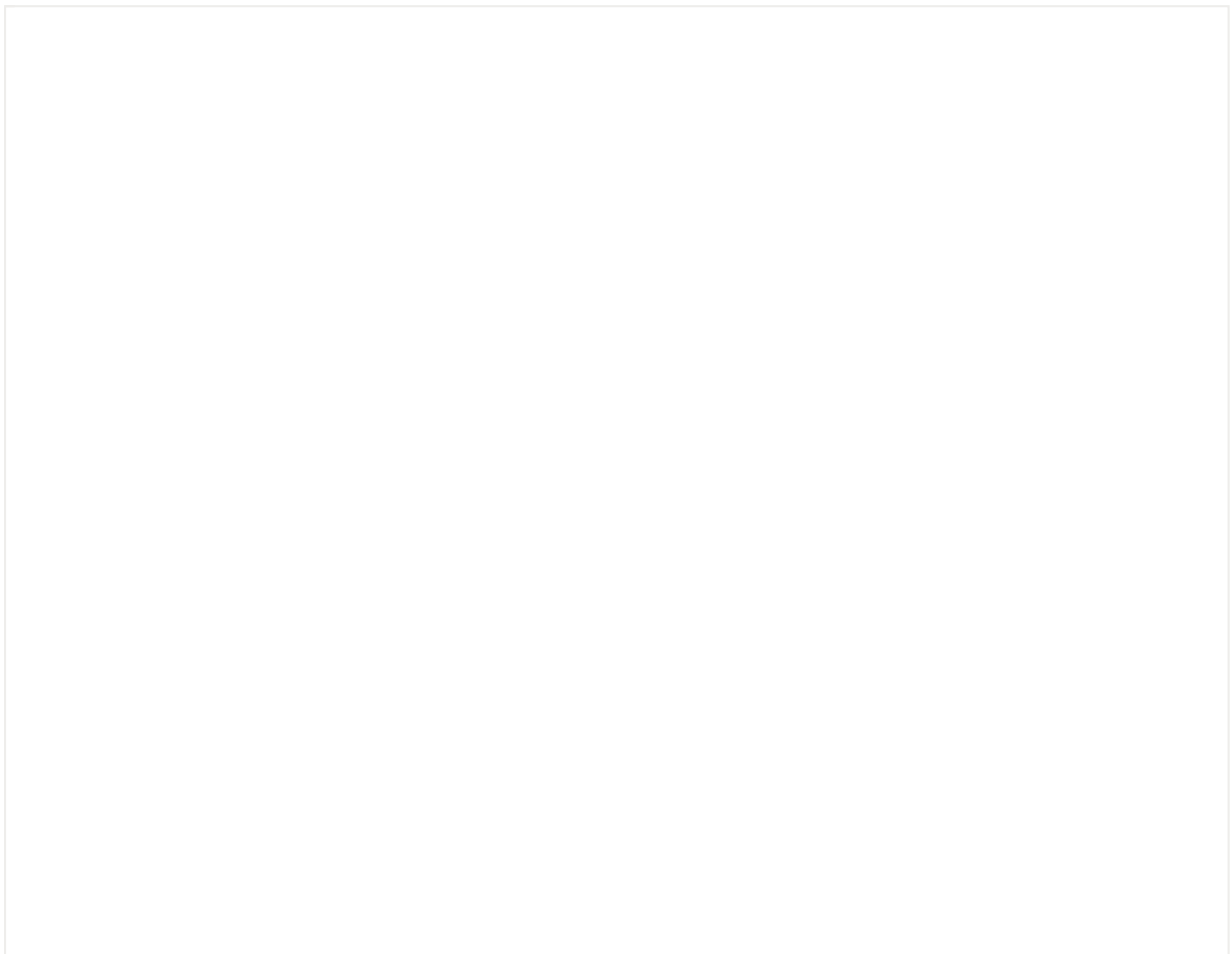


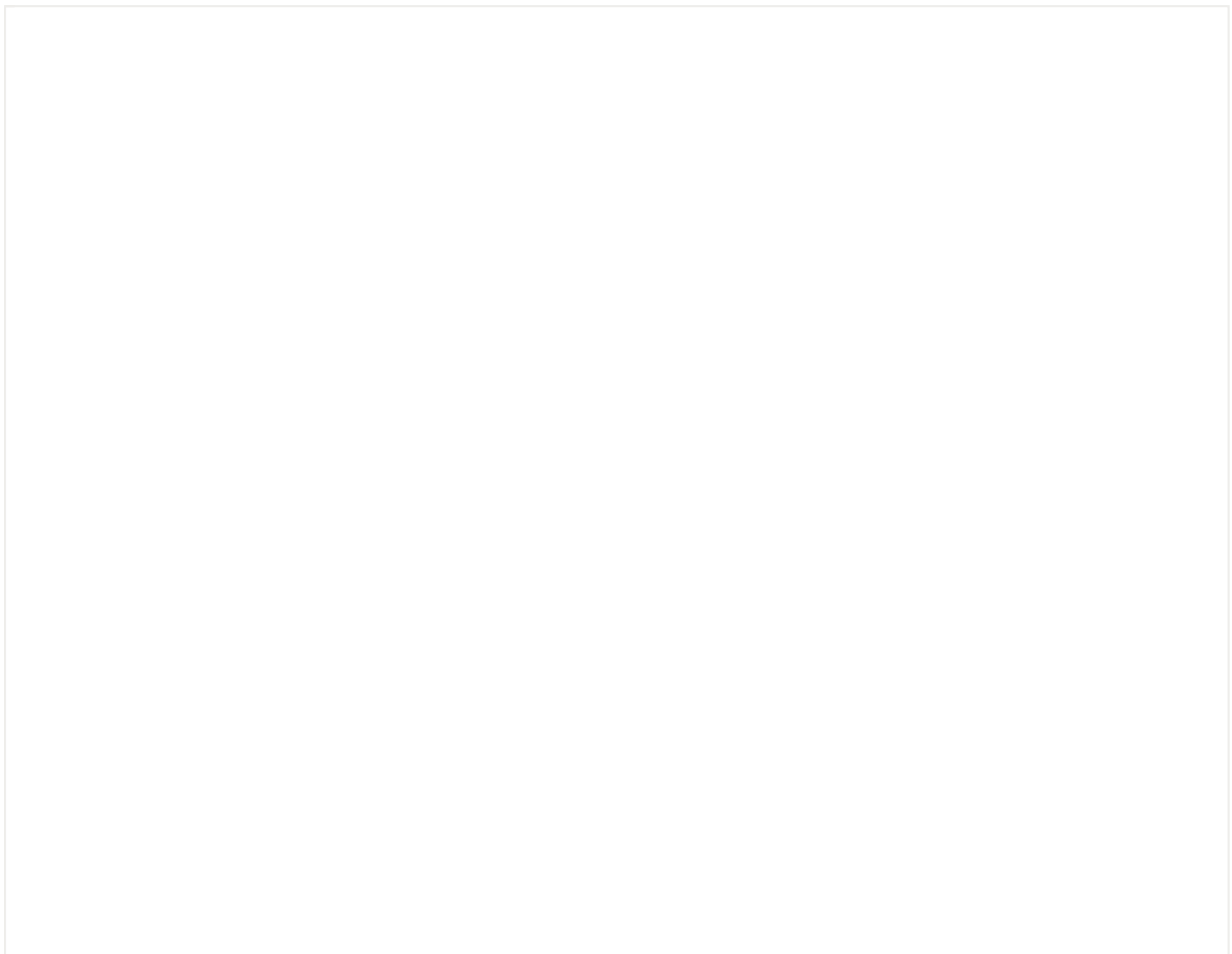




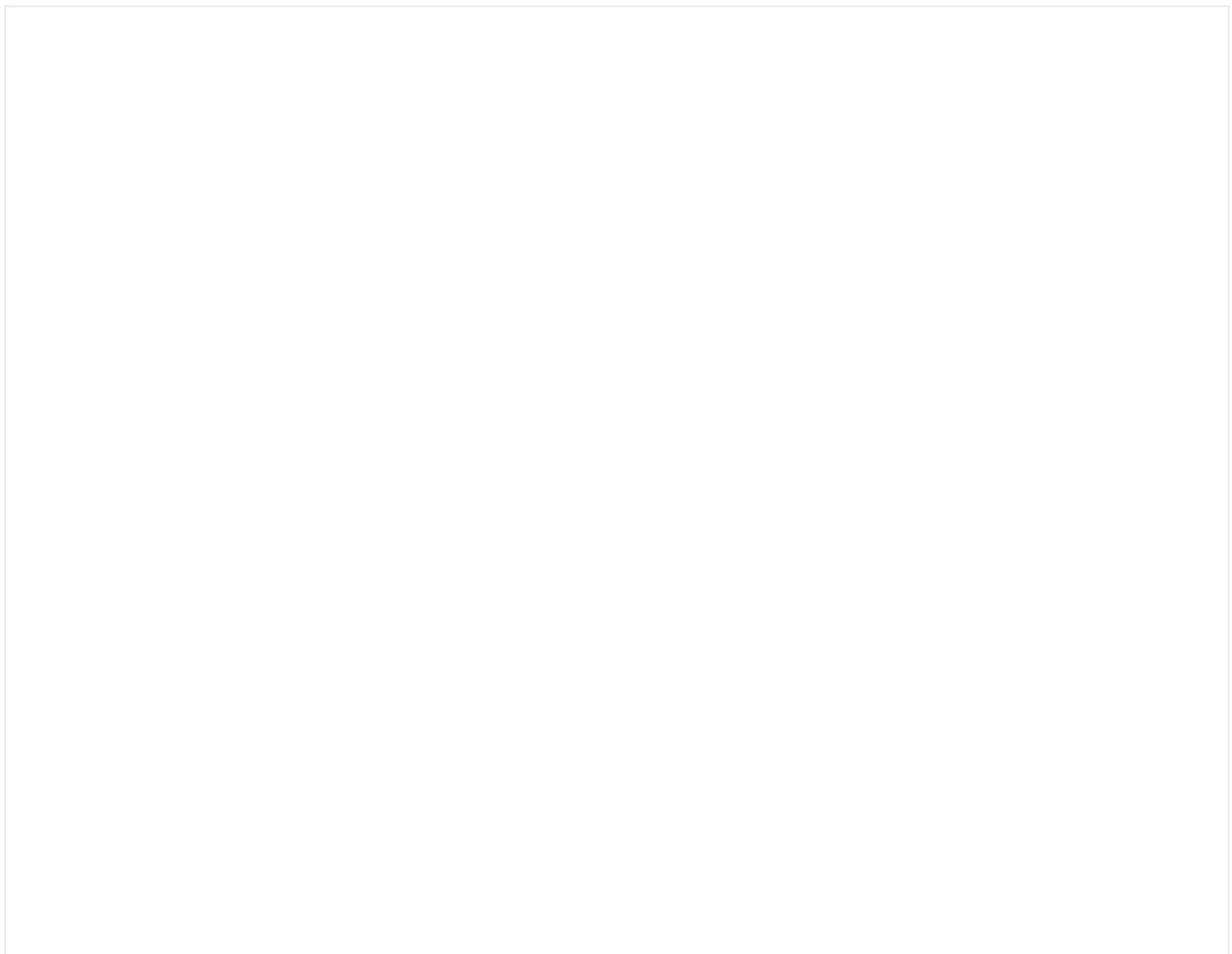


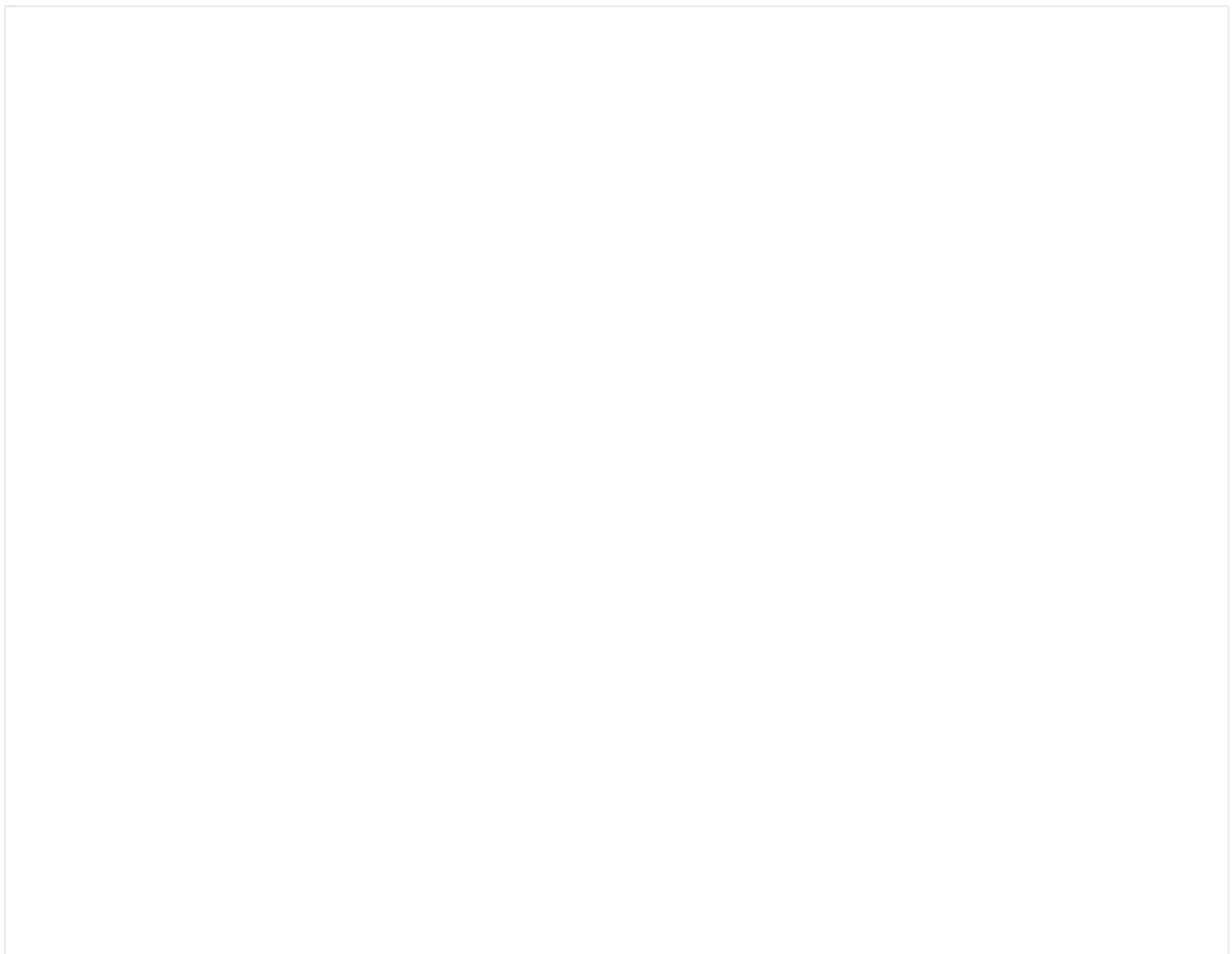


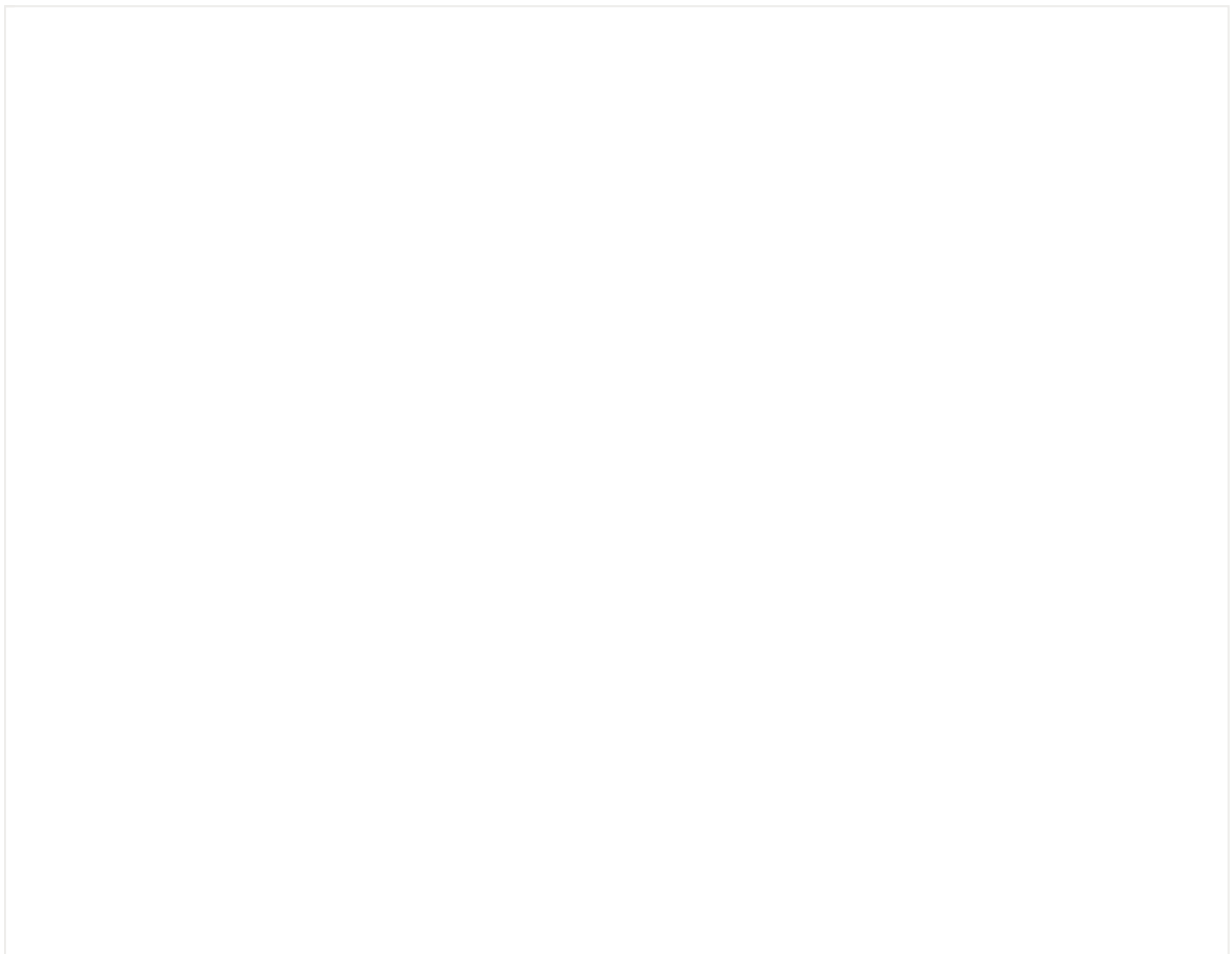




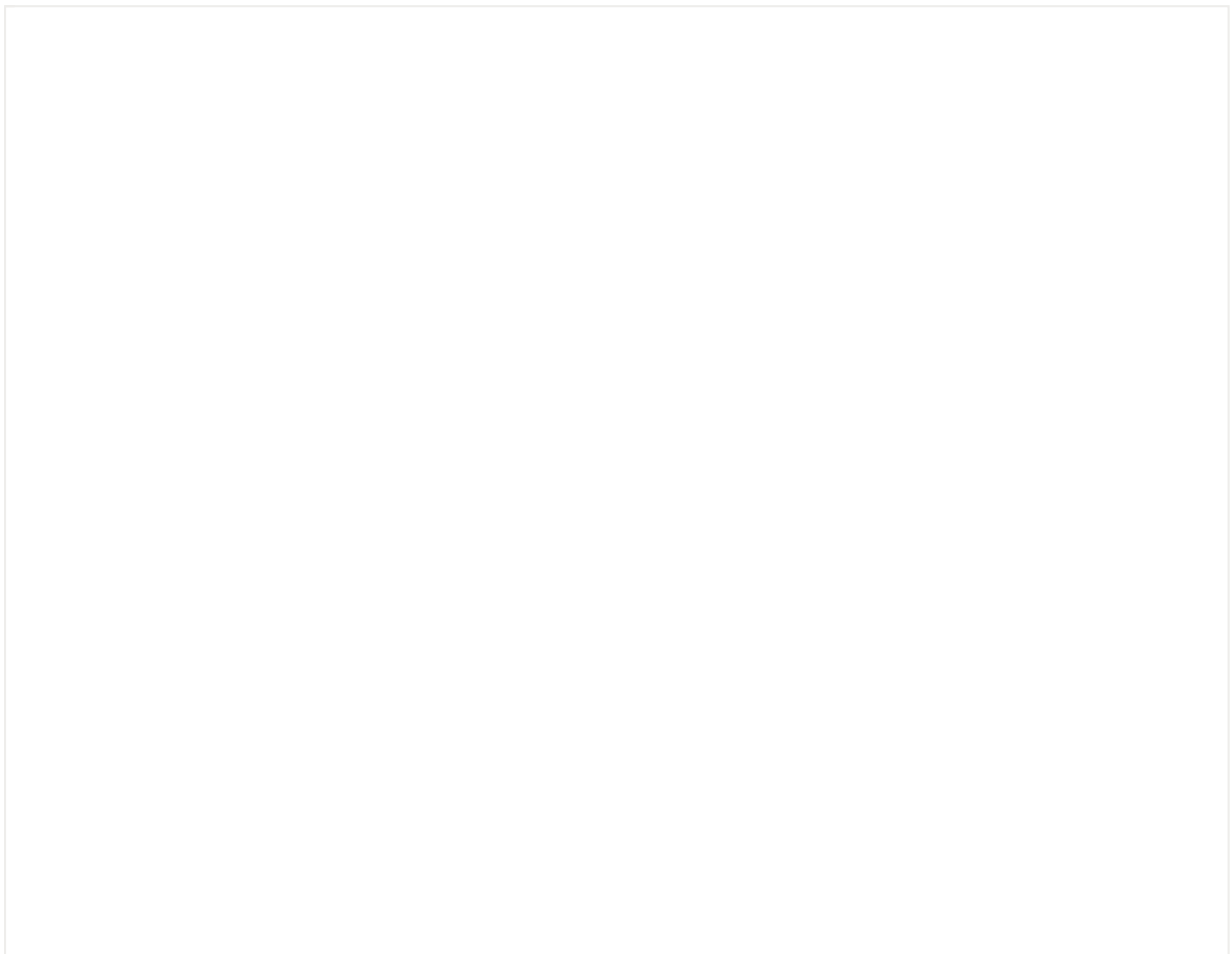


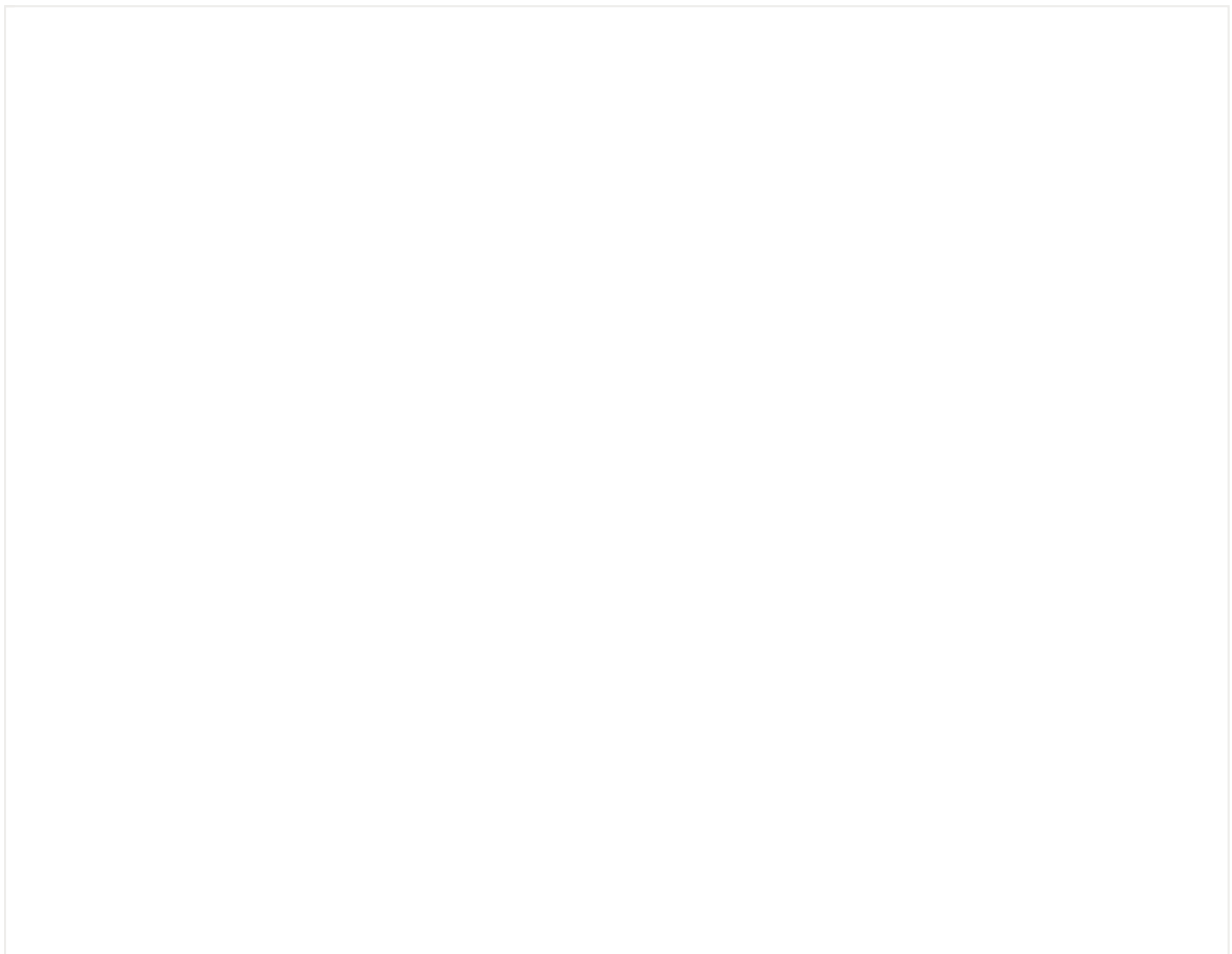


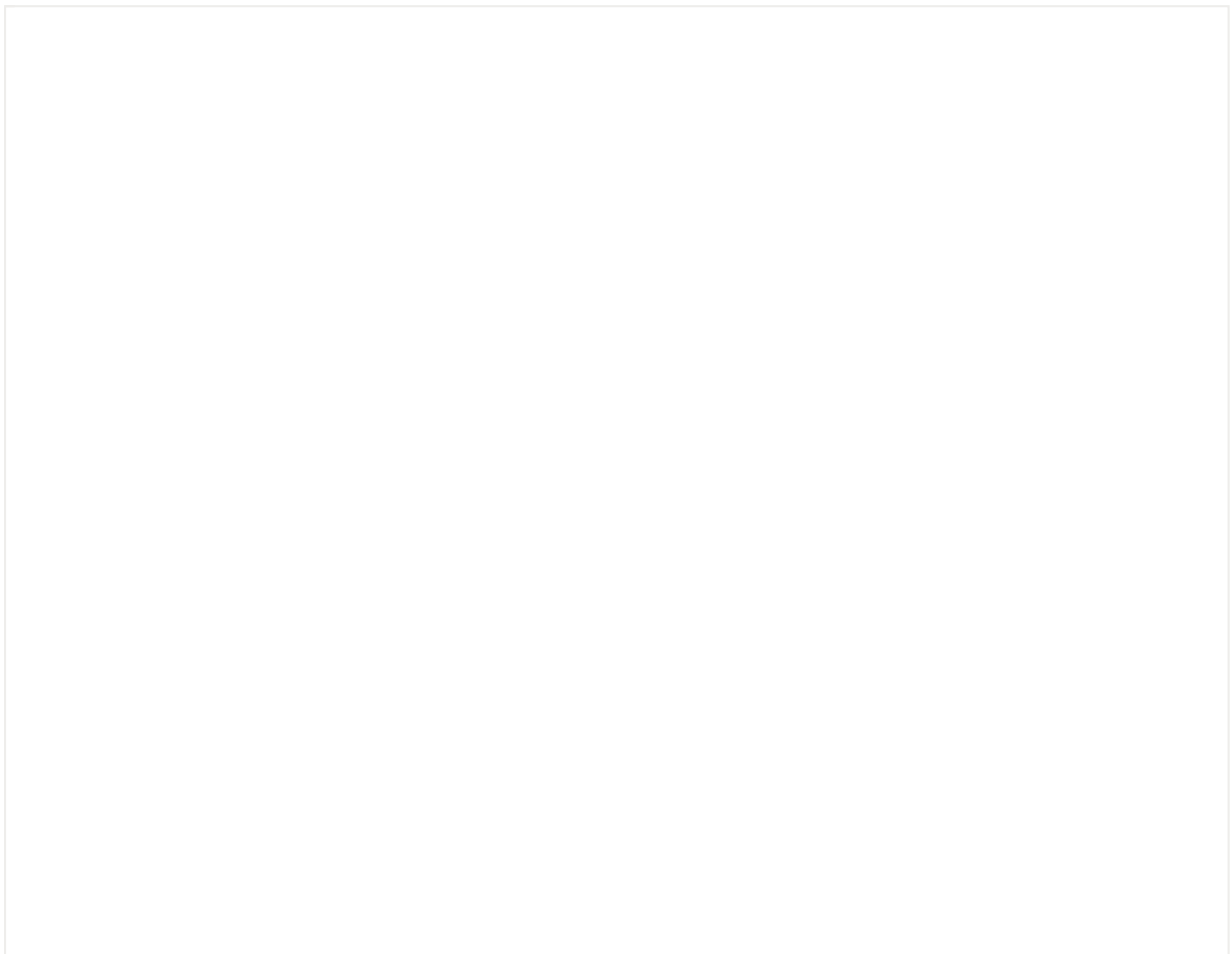


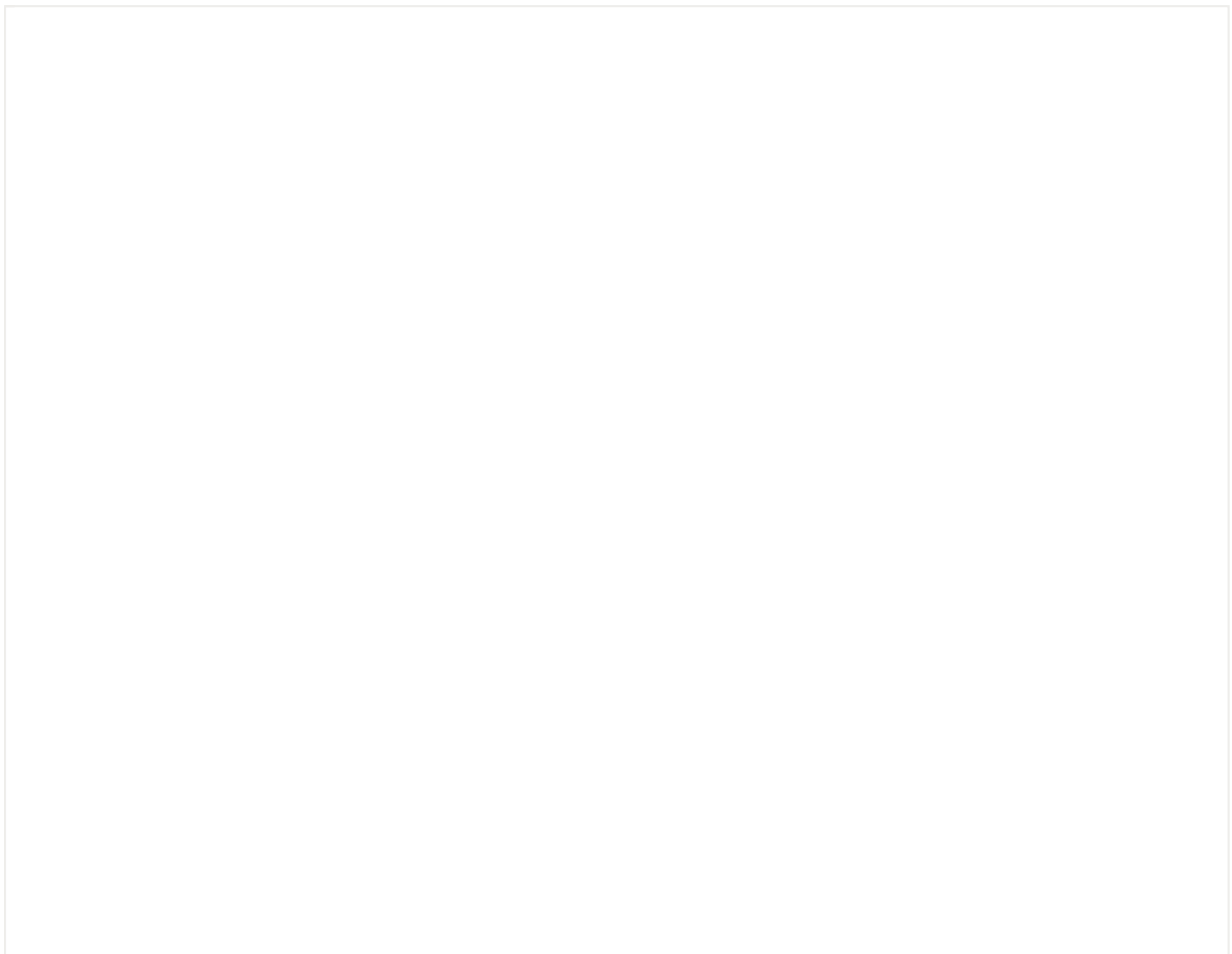


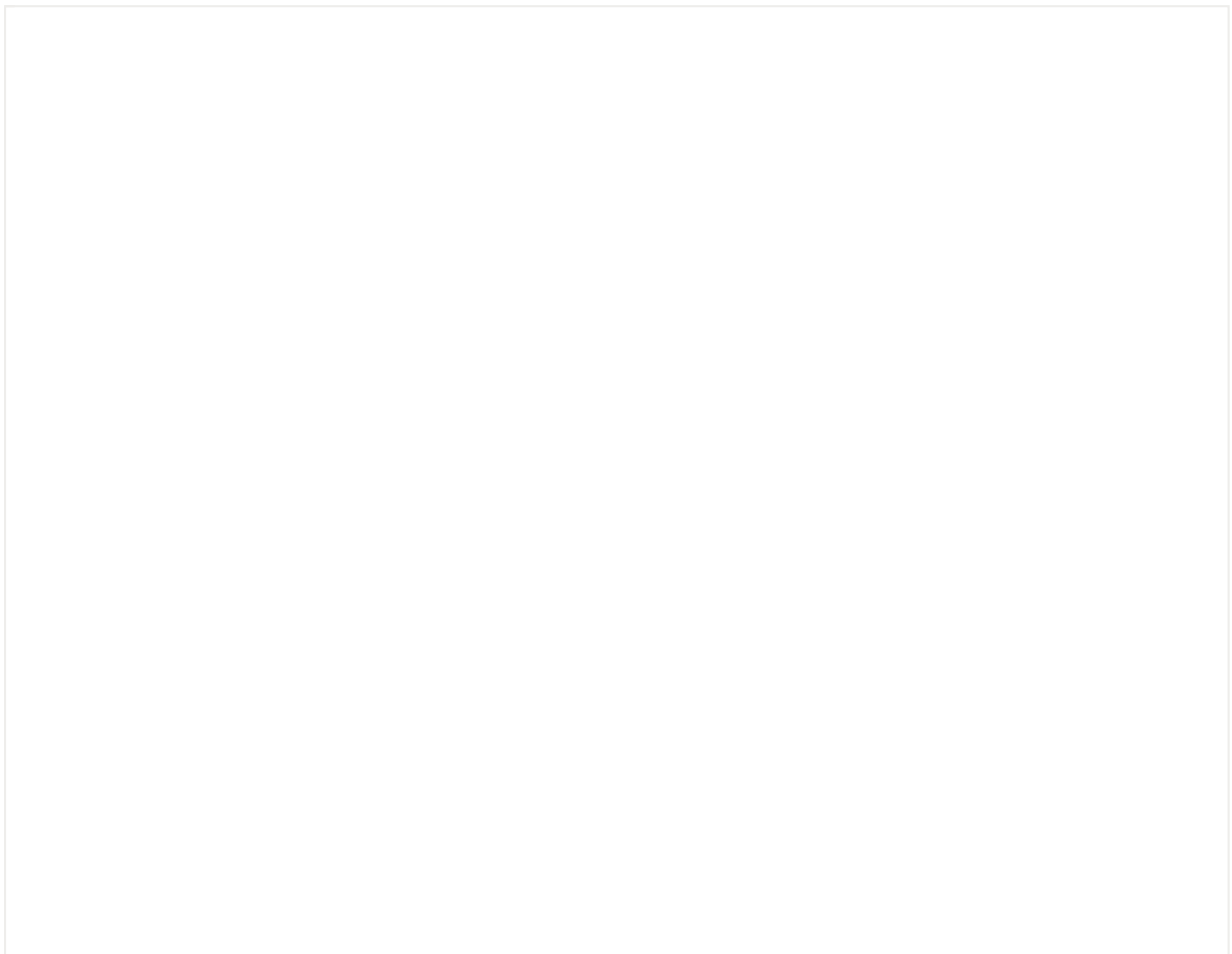


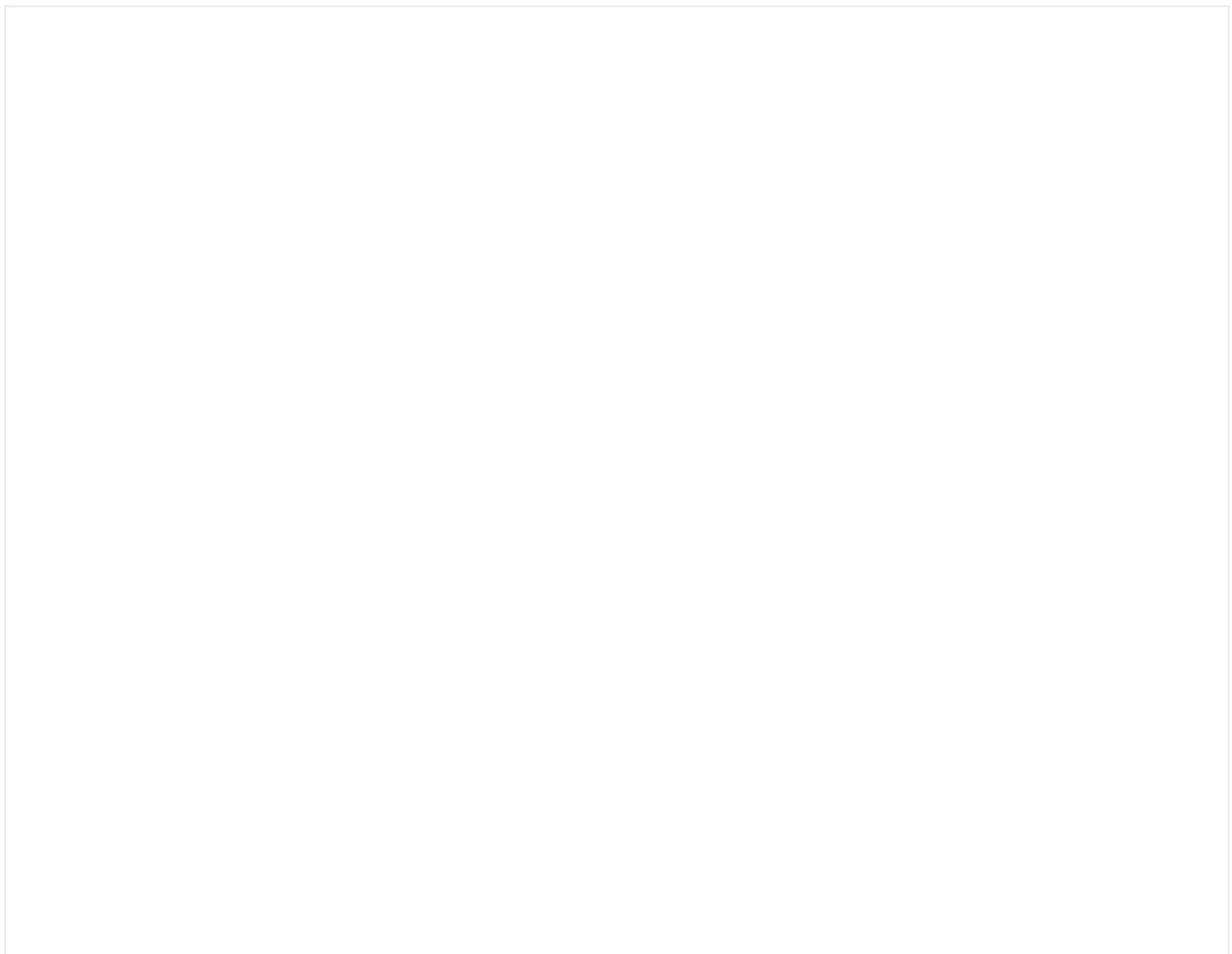


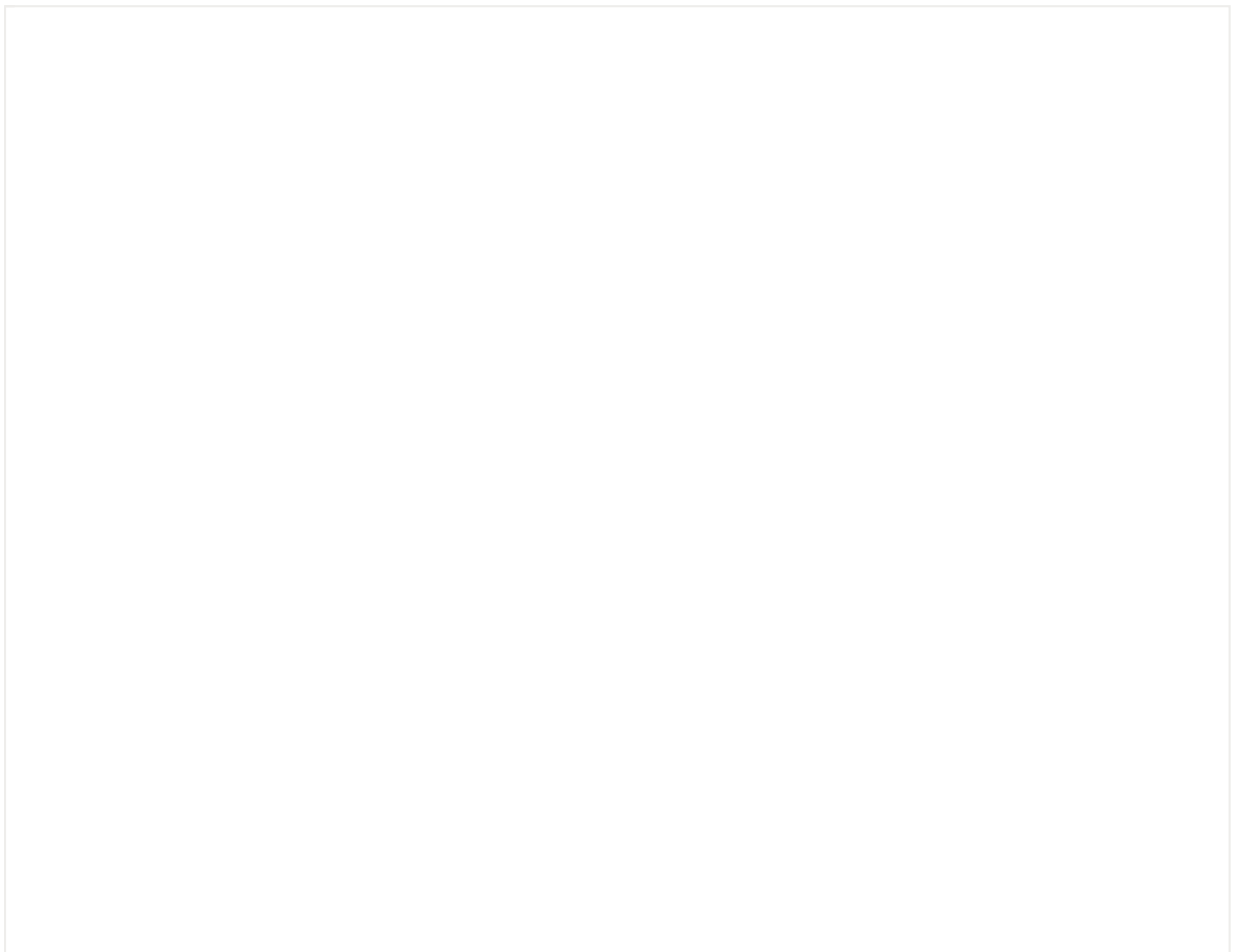


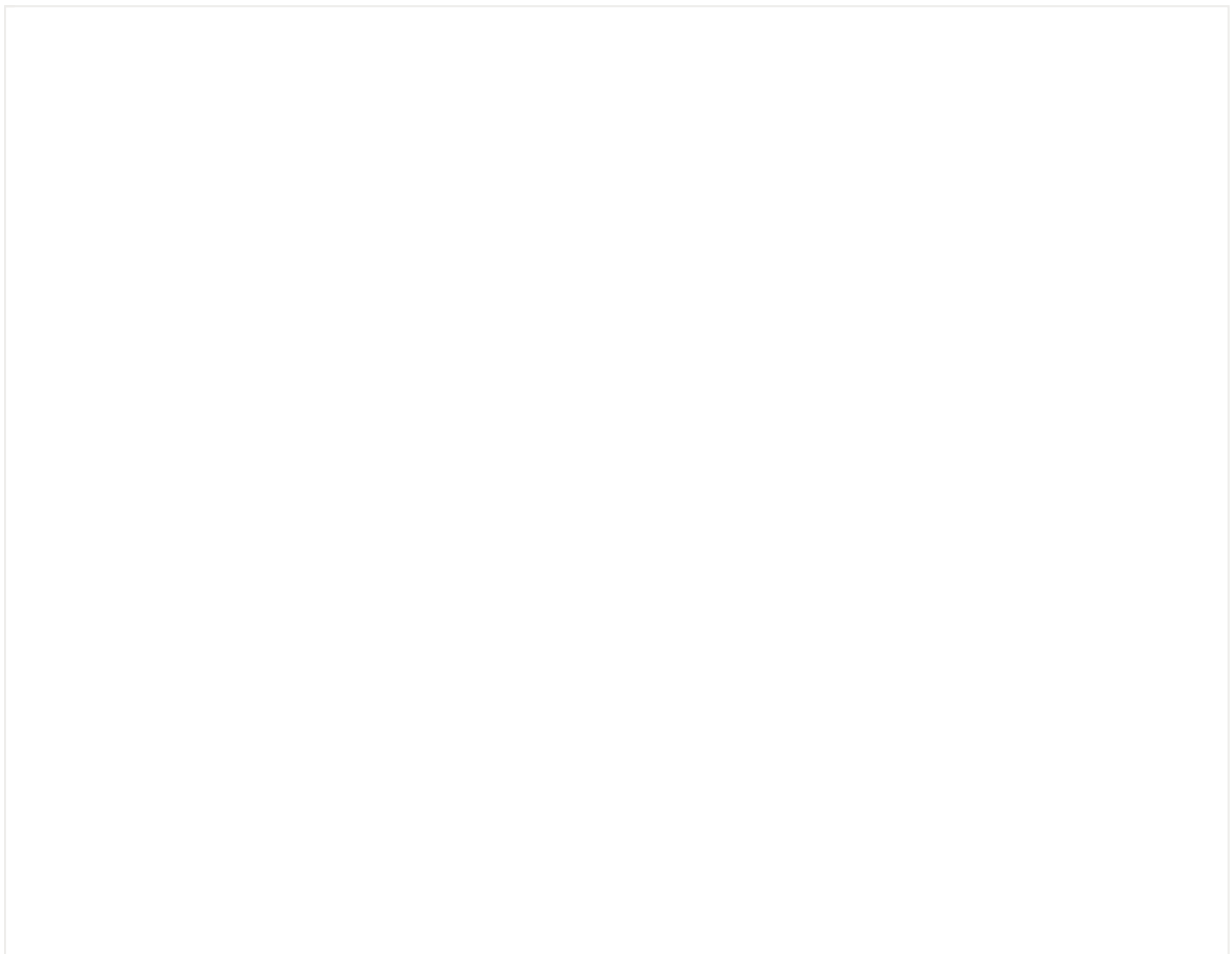




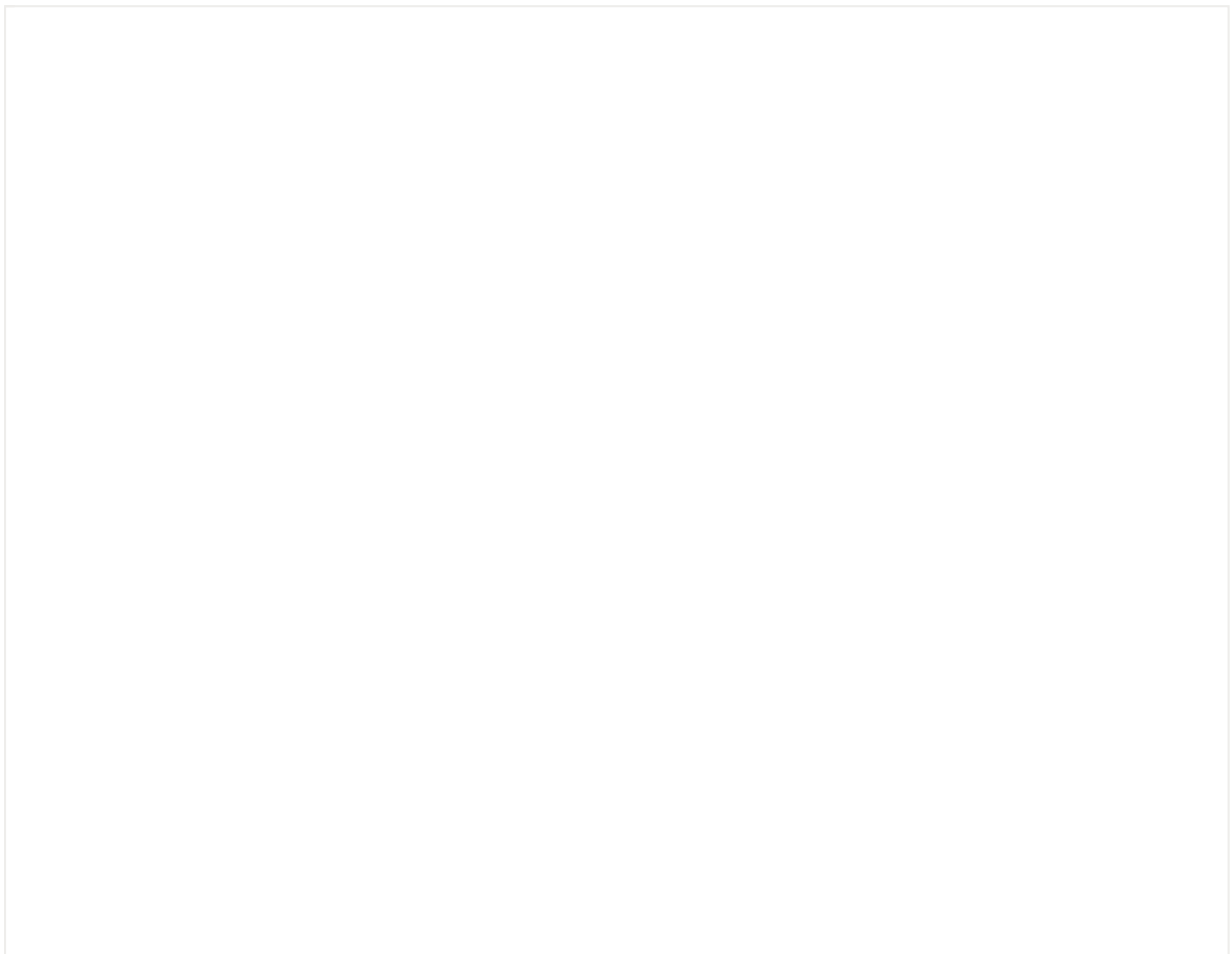


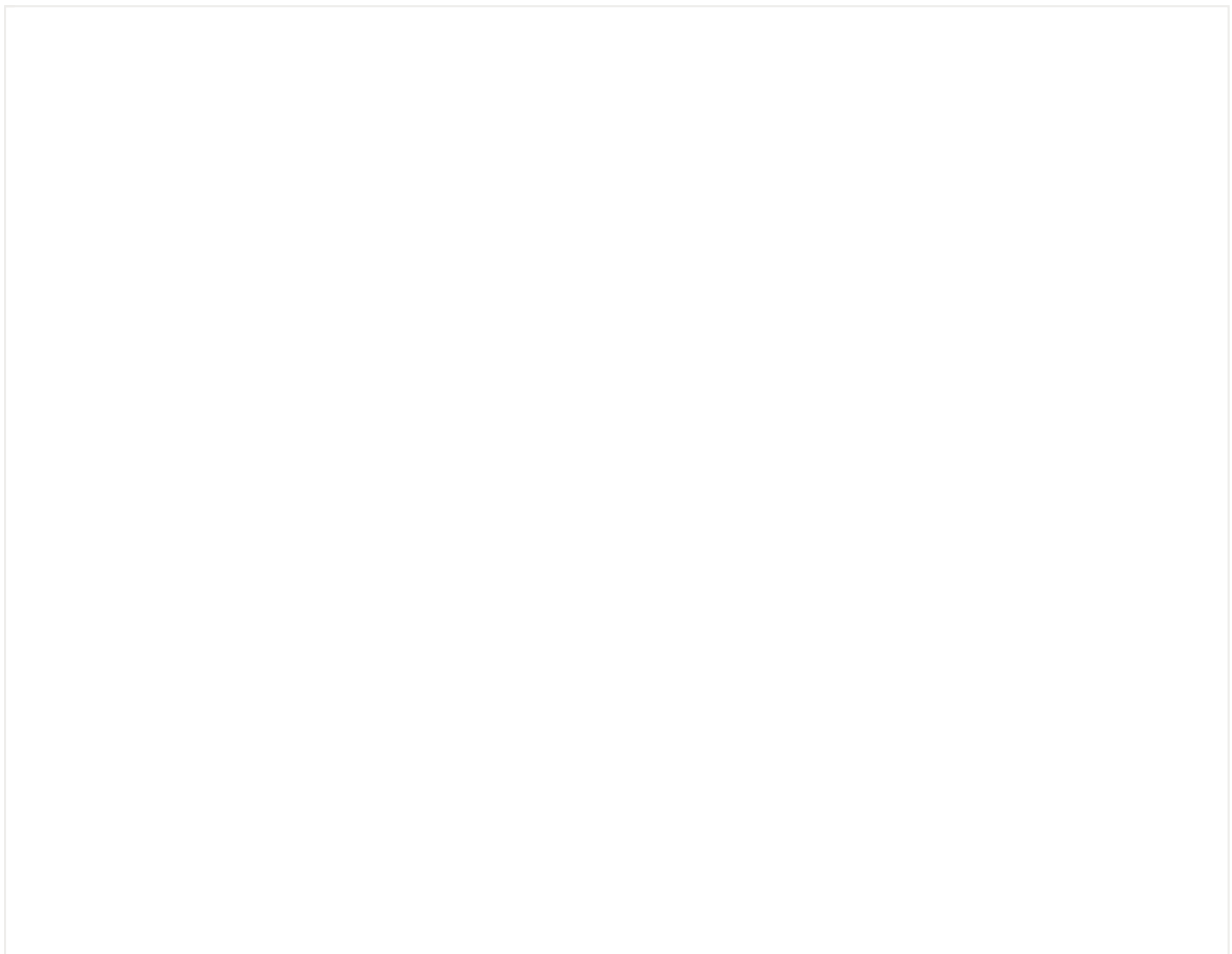


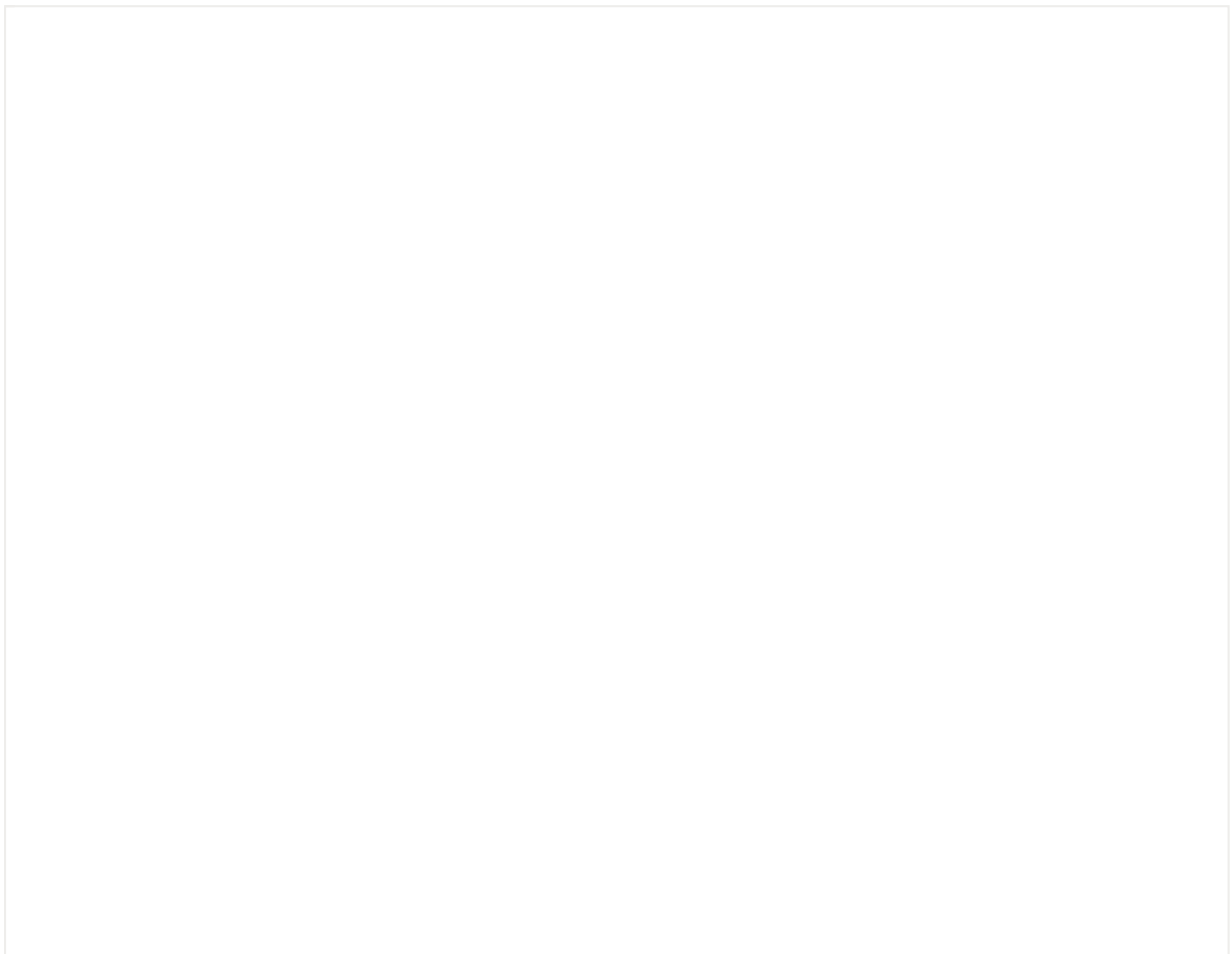


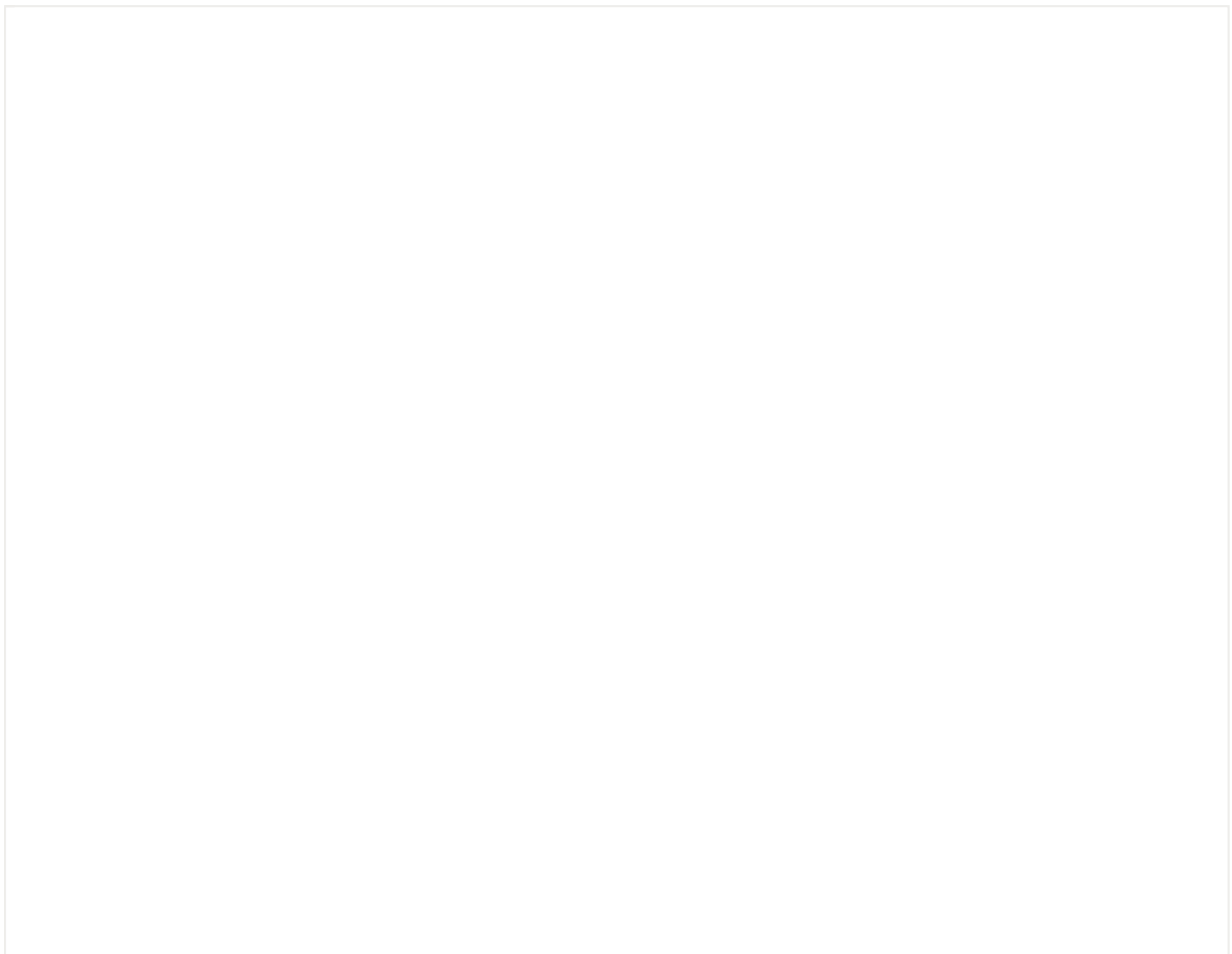


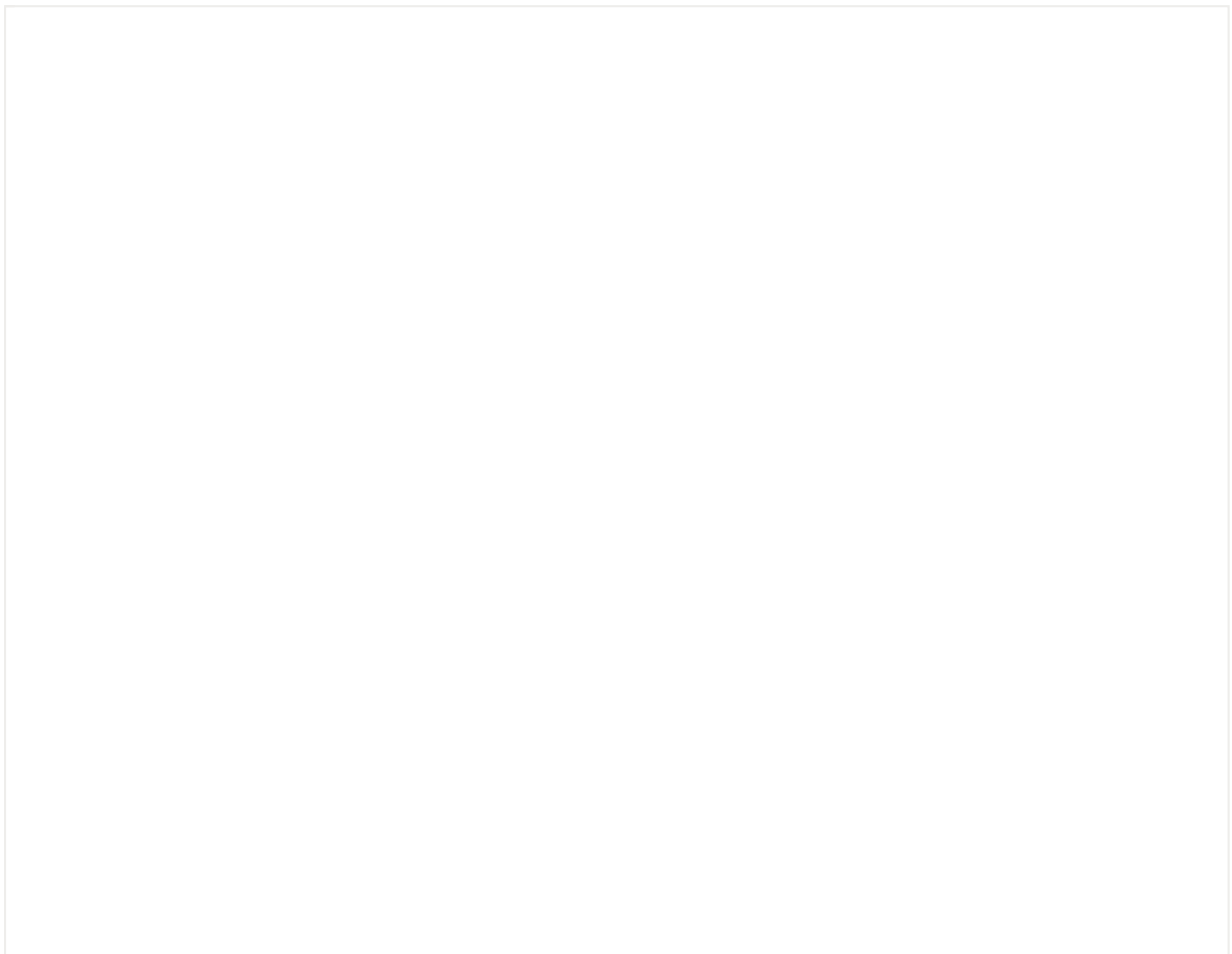


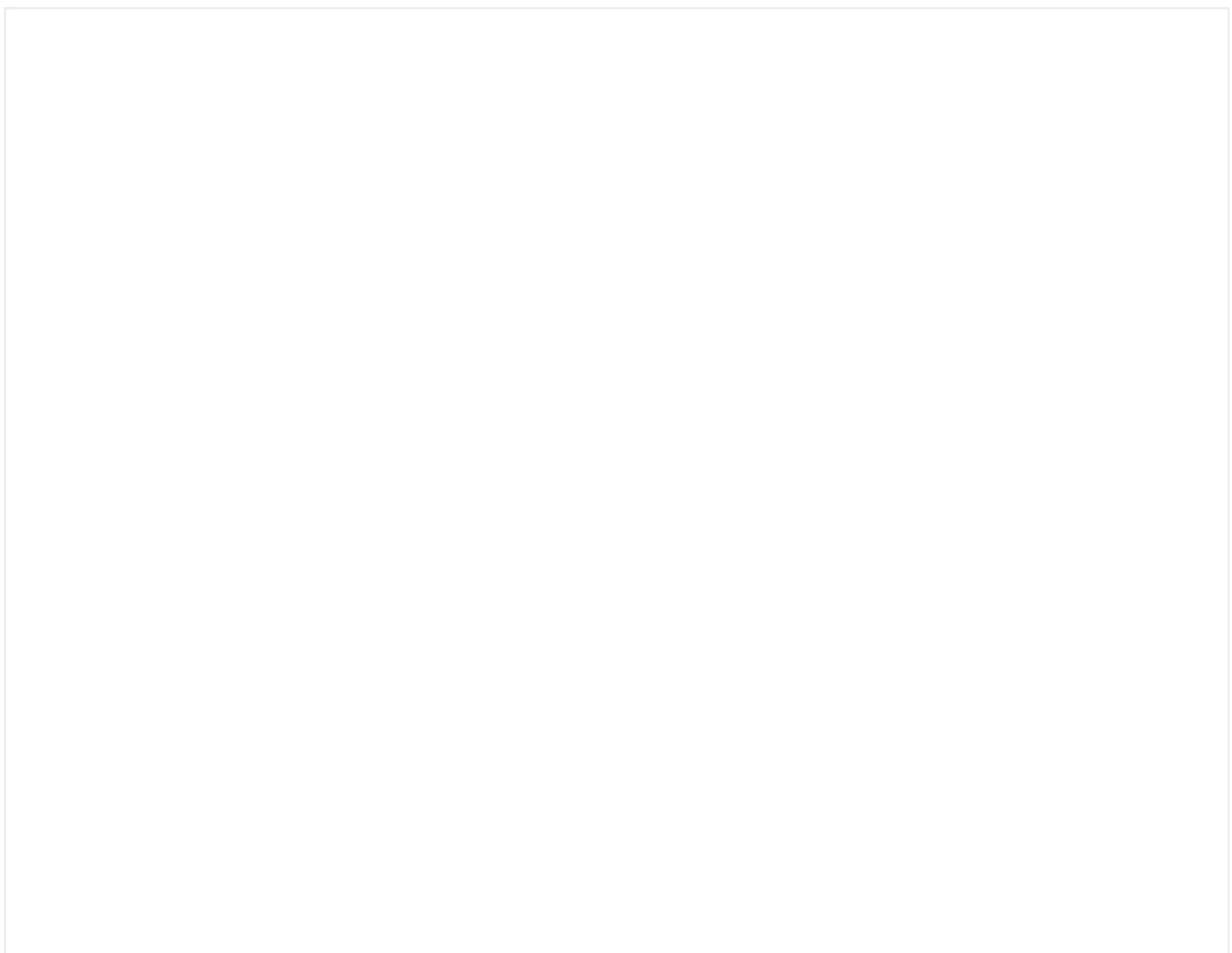


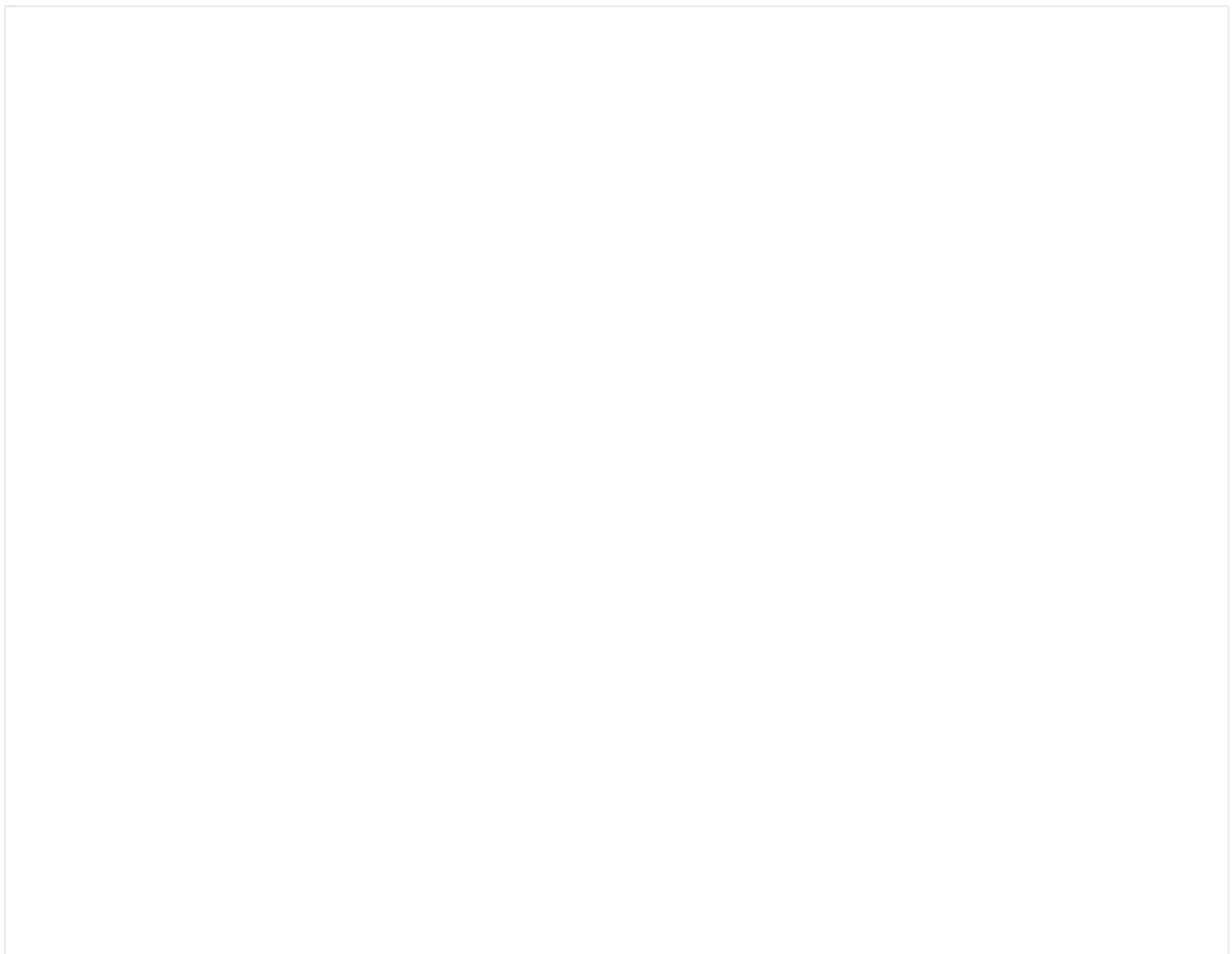


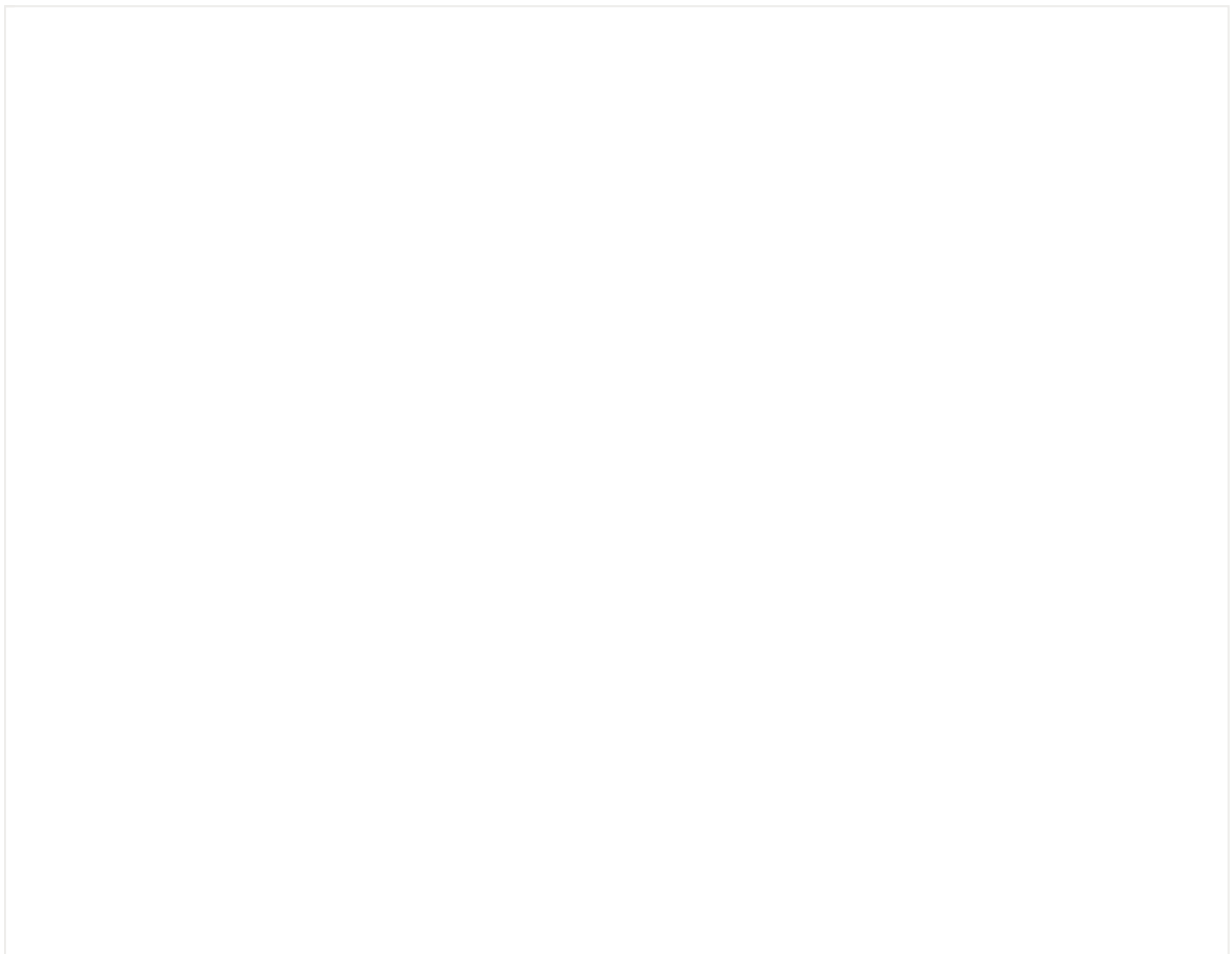
















## 致 谢

- Brian Hasselbalch
- Tara Gooen
- Teddi Lopez
- Tamara Ely

63



我们必须善于利用时间，并永远认识到，做正确事情的时机总是成熟的。

~ NELSON MANDELA

64

## 更多CGMP相关信息参见

批准前检查合规计划指南手册 (7346.832)

<http://wcms.fda.gov/FDAgov/downloads/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnsweronCurrentGoodManufacturingPracticescGMPforDrugs/UCM071871.pdf>

CGMP 主题相关

<http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm096102.htm>

问答 (Q&A)

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124740.htm>

65

### 参考文献

- [1] FDA. Investigation Operations manual 2017[EB/OL].[2018-05-19].  
<https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM127451.pdf>.

来源：国际药政通

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**注明：姓名+研究方向！**

