Breakthroughs that change patients' lives

Regulatory Inspections – Preparation, Execution and Deriving Value

Reflections of a Site Leader

Andrew Hodder
VP Operations – Pfizer Melbourne

My first Regulatory Inspection

US FDA March 1992 (27.5 years ago)

Thomas Arista

- Deputy Director of the Office of International Programs, India Office
- 35 Years with the FDA
- Investigator/National Expert Pharmaceutical/ Biotechnology

My role:

- Lead operator for a new API to be used for launch in the US
- “In the room” with the Inspectors for 5 days
- Explained the isolation, purification and blending process
- My source data:

Pfizer Melbourne

100+ years of Sterile Medicine Manufacture in Melbourne




1900's | **2000s** | **2015**

1915
David Bull Laboratories (DBL) starts manufacturing injectable pharmaceuticals in Melbourne

1973
Mulgrave site established and ampoule manufacture commences

1984
FH Faulding acquires DBL and in 1985 launches 1st oncology drug (Cisplatin)

2001
Mayne acquires FH Faulding. (generic oral business sold to Alpharma)

2007
Hospira acquires Mayne Pharma

2012
Hospira inducted into Manufacturing Hall of Fame Victoria

2013
Hospira approves technology in new Oncology capacity

2015
Pfizer acquires Hospira

2018
Site secures significant enhancements to support site & network strategy

DBL®

Faulding

mayne pharma

Hospira

Victorian Manufacturing Hall of Fame

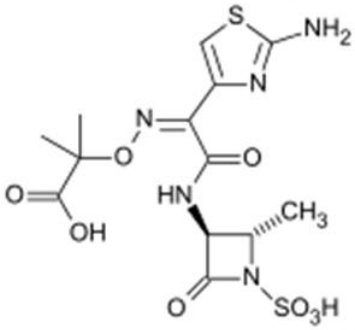
Pfizer

Pfizer BIOPHARMACEUTICALS GROUP

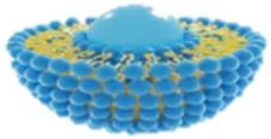
Pfizer Melbourne

Site Capabilities (500+ Colleagues – PGS & PharmSci)

- Sterile injectable products (liquid and lyophilised) in glass vials between 2–100mL
- Expertise in the manufacture of injectable oncology and potent products
- Capability to manufacture monobactams, a unique class of betalactams
- Experience with complex liposomal formulations and homogenization equipment
- Offer customers value-add packaging options with current Onco-Tain™ vial containment system and serialization
- Developing technology and skill for differentiated drug delivery systems



Aztreonam

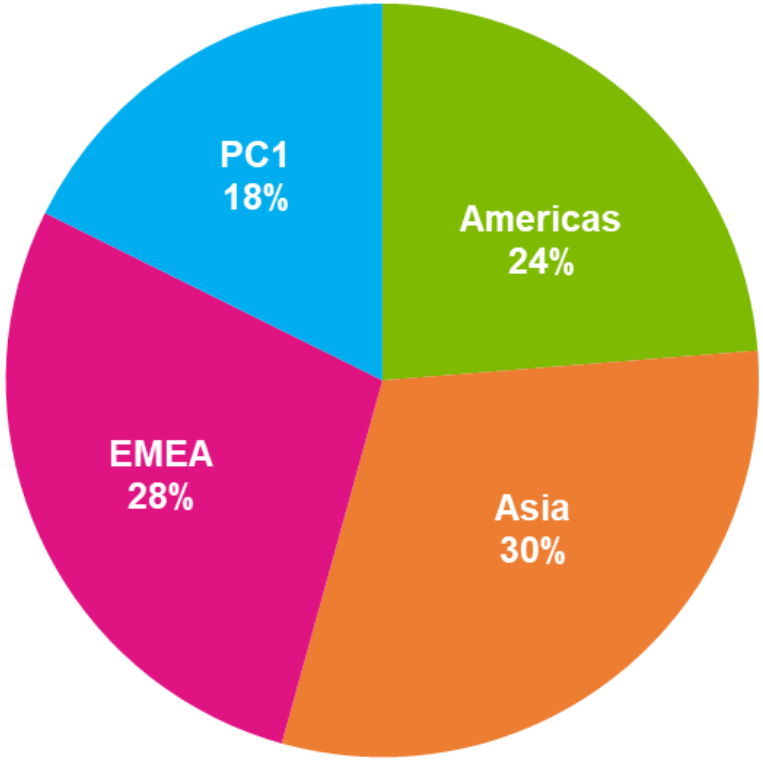


Liposomes

Our Markets and Regulators

A Global Supply Footprint

2018 Supply by Region



1. Regulatory Authority Inspections

TGA Health Safety Regulation

US- FDA

ANVISA

Republic of Turkey Ministry of Health

FDA 食品藥物管理署 Food and Drug Administration

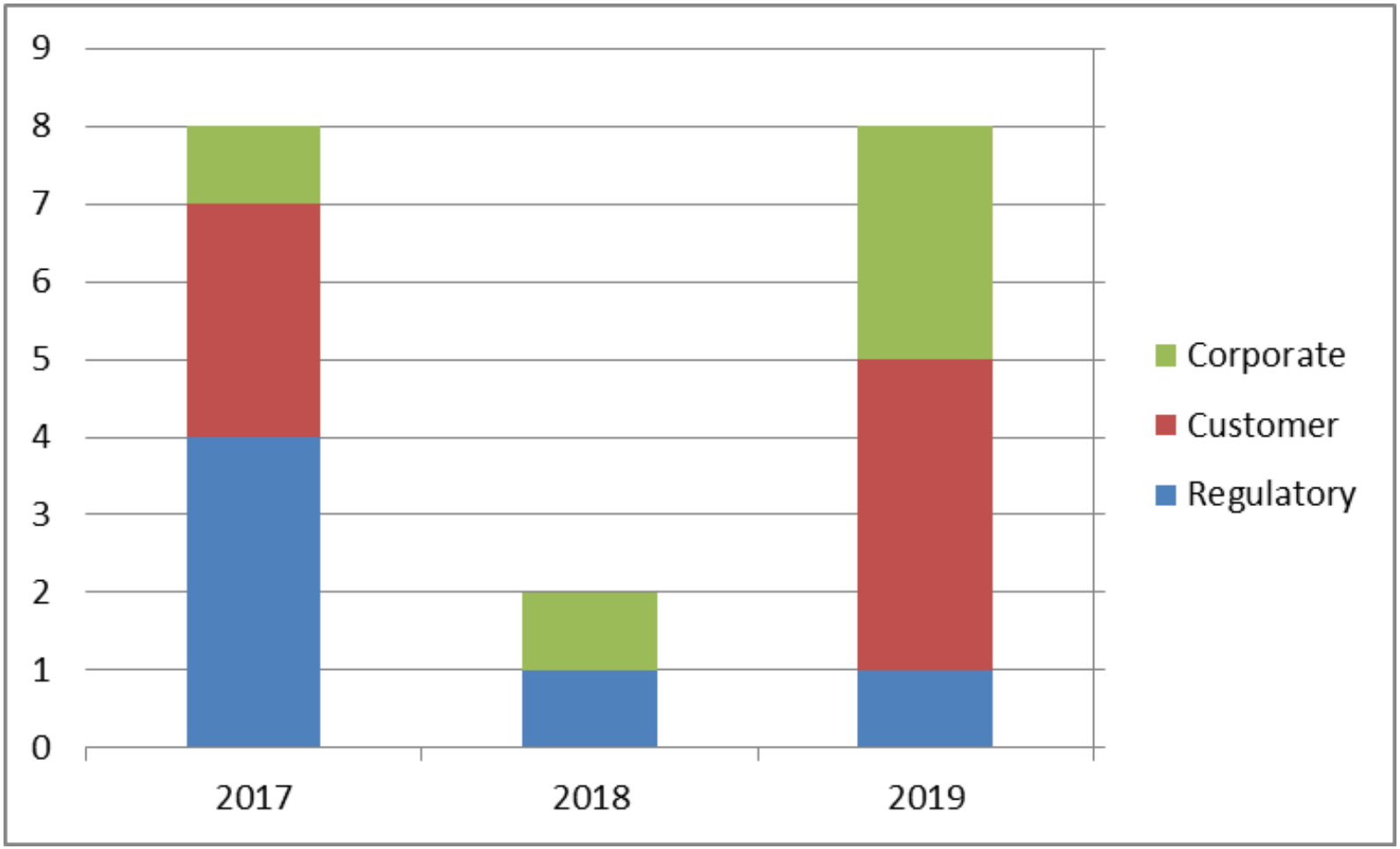
2. Contract Customers (PC1)
   (21 audits since 2014)

3. Annual Corporate Audits

4. Site Self Audits (SSA)

Inspection / Audit History

Number of Inspections / Audits 2017 - 2019



Inspection / Audit History

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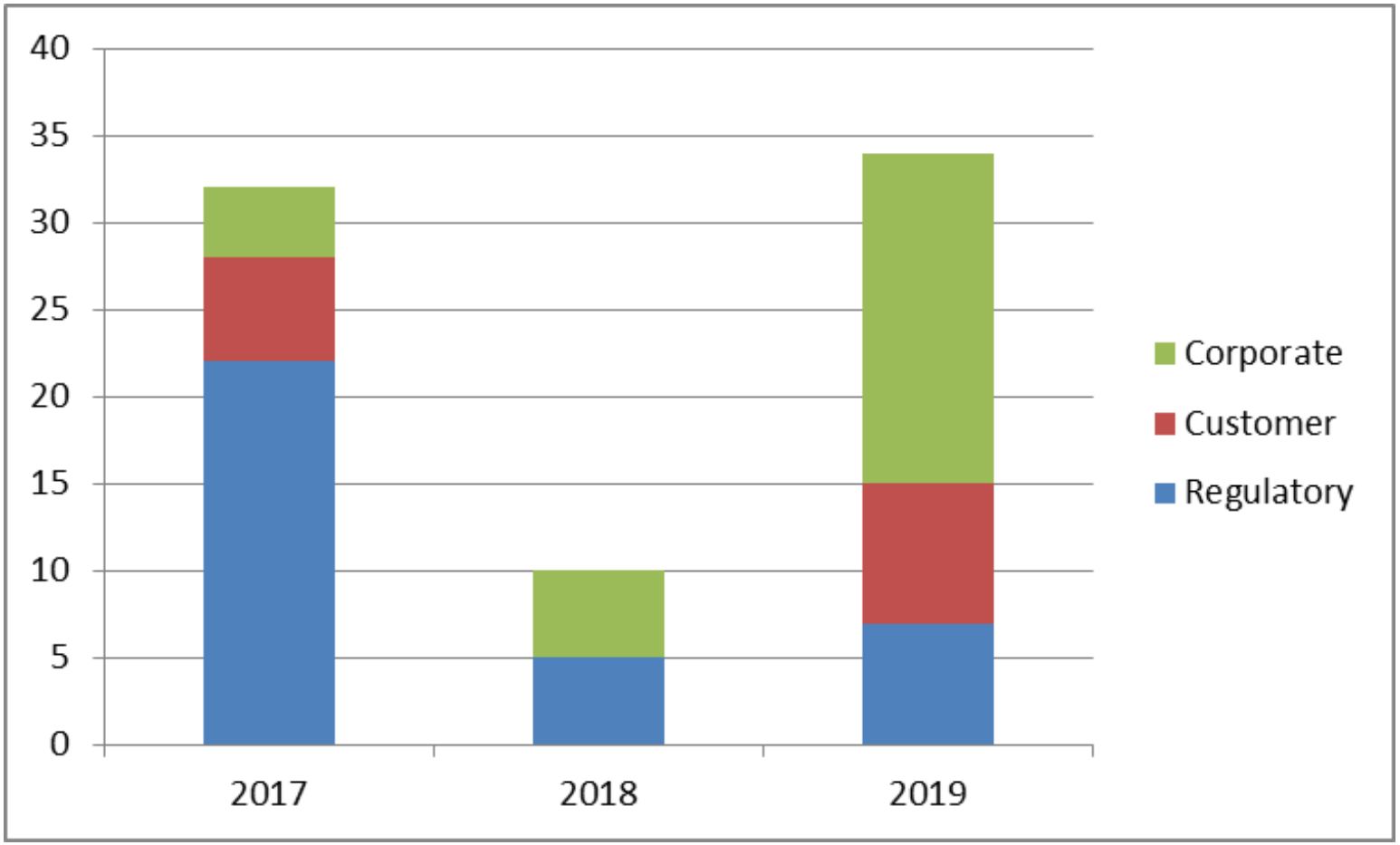
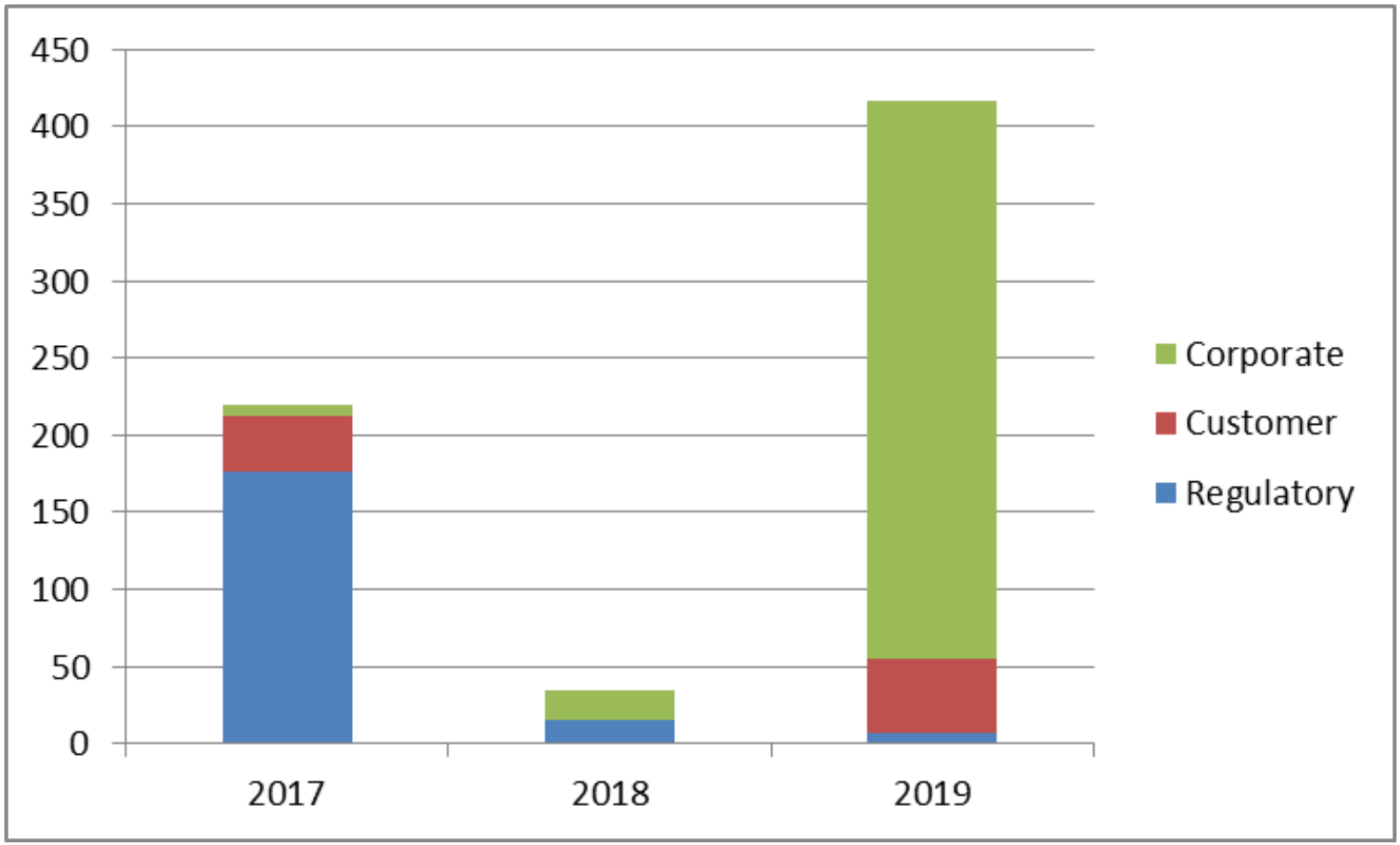


Inspection / Audit History

Number of Inspector / Auditor Days 2017 - 2019



Preparation for Inspections

Development of a Site Readiness Plan - Data

Ongoing governance (part of monthly meeting) is established for:

- Status of open regulatory commitments, internal observations and related items
- Status of any actions related to network regulatory observations
- Status of documentation updates and alignment with (internal) quality standards and regulatory requirements
- Identification of changes since last inspection (by agency) and status of any major site projects related to industry “hot topics”
- Alignment on accountability and timeline deliverables for action items
- Overall status of open records within deviation and corrective action management system
- Review of network inspections to assess for relevance.

Preparation for Inspections

Development of a Site Readiness Plan - Personnel

- The inspection is more than just the Quality function's responsibility
- Get the fundamentals right – Position Descriptions and associated training is current
- Review annual leave plans and approvals for key personnel
- Establish who are the Subject Matter Experts (SMEs) if not already identified and prepare them
- Determine if and what above site support may be needed (e.g. IT, Legal) and ensure their availability for inspection dates and times
- If required conduct refresher training on conduct for inspections
- Is there a "development" opportunity for a colleague to learn and gain experience
- Set expectations for colleagues that long days and personal flexibility may be required during the inspection

Preparation for Inspections

Establish Controls and Creating Alignment

- Inspection “base camp” and support mechanisms scheduled and in place
- Opening meeting scheduled and key personnel invitations sent (& accepted)
- Ways of working with inspector(s) agreed early to ensure successful execution:
  - Document provision – hard copy, electronic
  - Electronic recording requirements
  - Daily wrap ups – yes / no, morning / afternoon
  - Provision of meals and drinks
- Above site reporting frequency and methods throughout inspection – written or Webex or both?

Preparation for Inspections

We still need to run other parts of the Business in parallel……..

- Do any currently scheduled events need to be changed – business travel or site visitors?
- Who will cover for colleagues involved in the inspection?
- What other commitments are overlapping during the inspection:
  - Corrective action (Quality, EHS) commitments
  - Project milestones – e.g. FATs, SATs
  - Organisational restructures
  - Budget preparations
  - Critical supply commitments or product launches
  - Union agreements negotiations
- Global or corporate cultural events should be reset whilst still acknowledging on the date.
- Do we need to budget or forecast for the inspection?

“The Inspection is the main thing but it can’t be the only thing”

More than Compliance

Deriving extended value from Regulatory Inspections / Requirements

Change your lens for other benefits:

- Colleague development
- Organisational redesign
- Strategic investments – capital and personnel
- New market opportunities and extra volume
- Continuous improvement mindset

Can we achieve and maintain compliance with a commercial flair?

Strategic Value

Quality Compliance – is it an Order Qualifier or Winner?

- A recent forum with Directors of Pharmacy ranked the importance of four considerations (safety, quality, supply, cost) in their product selection.

ORDER QUALIFIERS	THRESHOLD	ORDER WINNERS
Safety **Quality**		**Supply** **Cost**

- All are important but some are different.
- You can't "win the race" if you don't qualify.
- Supply and cost will follow with robust quality performance

In Summary

Regulatory Inspections are a substantial investment, however…

- They are necessary and required elements of the industry in which we enjoy working in and for the patients we ultimately serve
- It keeps a site relevant, contemporary and protects their right to operate
- Provides the opportunity for colleagues to learn and develop
- Provides the opportunity to develop strategies (e.g. investments, marketing) that achieve both compliance and commercial outcomes

Thank you