

# A Manufacturer's Perspective – Successful Compliance Outcomes Across Multiple Markets



*“To Be a Growth-oriented, Trusted,  
and Reliable Resource, Delivering  
Innovative Solutions for Our  
Customers’ Success”*

**Parnell - 2020**

## Parnell – Manufacturing Vision

How Parnell Manufacturing Contributes to the Overall Vision?

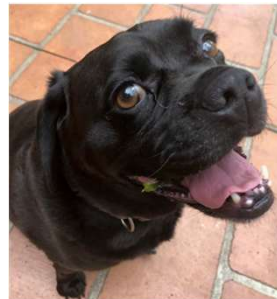
*Right Product,  
at the Right Time, at the Right Quality  
= Customers Success*

*Manufacturing Leadership Team - 2024*

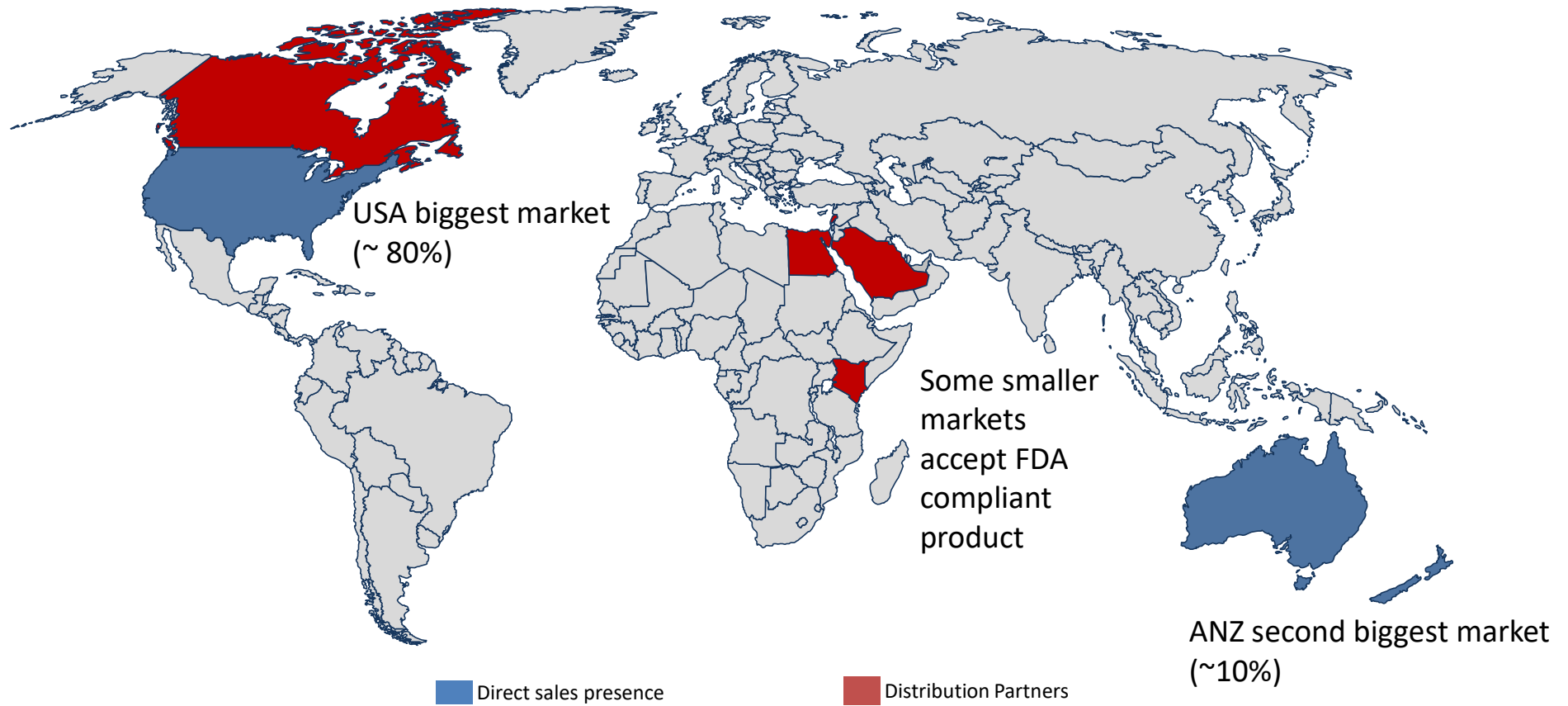
## What does Parnell Do?

- Veterinary pharmaceutical business focused on developing, manufacturing and commercialising innovative animal health solutions across three key business units:






- Production Animal
- Companion Animal
- Contract Manufacturing






# Where Does Parnell Sell?



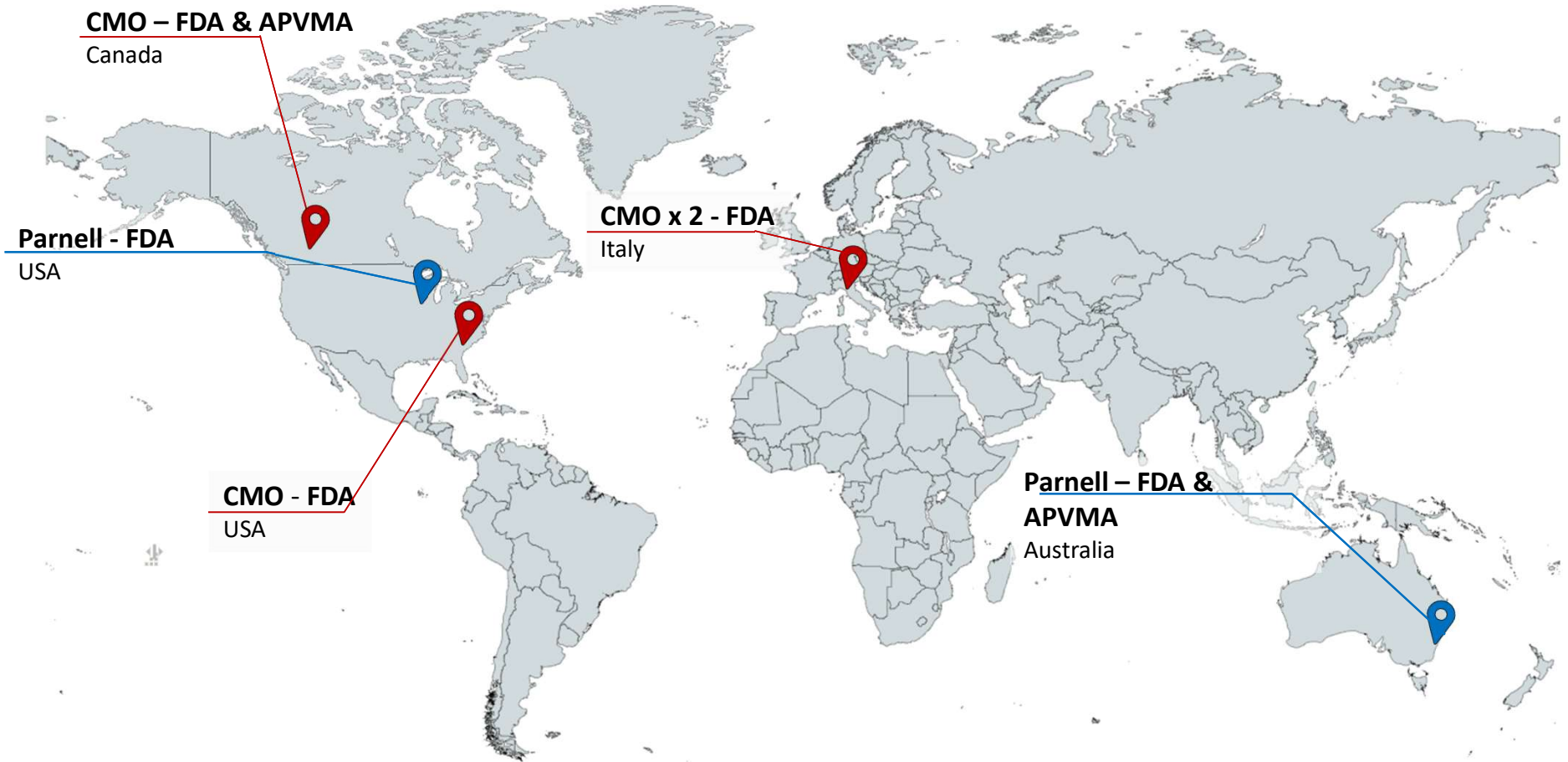
# What does Parnell Sell?

Key Division	Parnell Brands
<p>Production Animal</p>	<ul style="list-style-type: none"> <li>Two reproductive hormone products used to facilitate oestrous synchronization                             <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>GONAbreed</p>  </div> <div style="text-align: center;"> <p>estroPLAN</p>  </div> </div> </li> </ul>
	<ul style="list-style-type: none"> <li>Digital technology (mySYNCH) used to optimise reproductive outcomes being the number one economic driver on a dairy operation                             <div style="text-align: center;">  </div> </li> </ul>
	<ul style="list-style-type: none"> <li>Two antibiotics product for bovine respiratory disease (RESPIRmycin &amp; nixiFLOR)                             <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>RESPIRmycin</p>  </div> <div style="text-align: center;"> <p>nixiFLOR</p>  </div> </div> </li> </ul>

# What does Parnell Sell?

Key Division	Parnell Brands
Companion Animal	<ul style="list-style-type: none"> <li>Four products for anaesthesia and sedation</li> </ul> <div style="display: flex; justify-content: space-around; text-align: center;"> <div data-bbox="541 548 869 630"> <p>PARNELL BRAND DEXMEDETOMIDINE HYDROCHLORIDE INJECTION</p>  </div> <div data-bbox="898 548 1226 630"> <p>CONTRASED™ (ATIPAMEZOLE HYDROCHLORIDE) INJECTION</p>  </div> <div data-bbox="1255 548 1549 630"> <p>PROPOFOLVET MULTIDOSE (PROPOFOL INJECTABLE EMULSION)</p>  </div> <div data-bbox="1591 548 1885 630"> <p>PARNELL BRAND ISOFLURANE INHALATION ANESTHETIC</p>  </div> </div>
	<ul style="list-style-type: none"> <li>Two products to treat Osteoarthritis - Zydax – an injectable &amp; Glyde – a soft chew nutraceutical</li> </ul> <div style="display: flex; justify-content: center; gap: 50px;">   </div>
	<ul style="list-style-type: none"> <li>One product for euthanasia</li> </ul> <div style="text-align: center;"> <p>PARNELL BRAND PENTOBARBITAL SODIUM AND PHENYTOIN SODIUM</p>  </div>

# Where does Parnell Manufacture?



# How does Parnell ensure Successful Compliance Outcomes Across Multiple Markets?

1. Our Regulatory Approach
2. Our Quality Compliance Approach
3. We want to do the right thing

# 1. Our Regulatory Approach

- Regulatory Resource locations:
  - 75% in US because that's our biggest market
    - Also geographically close to Canada
  - 25% in AU - ANZ is second biggest market

## 1. Our Regulatory Approach

- How do we understand the requirements for each market?
  - Our regulatory team know the different markets without knowing them all in detail
  - They know FDA, ANZ in detail but have understanding of other markets built from experience/organisational knowledge
  - Working with distribution partners who own the marketing authorization e.g. Israel, Kenya

## 2. Our Quality Compliance Approach

- We follow PIC/S, why?
  - Sets the benchmark for a majority of the world
    - 50+ members across the globe
  - Several of our markets are PIC/S member including FDA, Canada, Israel
  - All our CMO's manufacture in PIC/S member countries as does Parnell (US)
  - Auditing vendors to PIC/S cGMPs

## 2. Our Quality Compliance Approach

- What else?
  - Leverage globally accepted guidance documents
    - VICH e.g. stability, method validation
    - ICH e.g. Quality Risk Management
    - PDA e.g. CCS, aseptic processing + many others
    - ISO e.g. 14644 for clean rooms

## 2. Our Quality Compliance Approach

- What else?
  - One QMS that covers all markets
    - We try to avoid creating different processes for different markets
    - Where necessary, have market specific processes e.g. FAR for FDA
    - An eQMS makes this easier

## 2. Our Quality Compliance Approach

### ■ What else?

- If we have an issue, e.g. for a batch going to multiple markets, understanding what needs to be done for each relevant market
- Doesn't matter if you “over comply” for some markets, better to default to worst case

## 2. Our Quality Compliance Approach

- What else?
  - The right team
  - The right people
  - The right number
  - The right roles

### 3. We want to do the right thing

- More than just following the regulations
  - Quality a Daily Habit
  - Slow down to finish faster

***Principle 10 - "Sterile and safe products all the time"***

- Ensure the safety of Parnell's products through assurance of identity, strength, purity and efficacy
- Everything we do, we do with our customers in mind
- 'Right first time' mindset



## Inspection Success Stories

- FDA 483's
  - 2019, 9 days = 0 – No Action Indicated (NAI)
  - 2024, 8 days = 4 – Voluntary Action Indicated (VAI)
    - 2 related to a new product waiting approval
  - No Official Action Indicated (OAI) or warning letters!
  - OAI = something serious!!

## Inspection Success Stories

- APVMA Observations, 5 days
  - 2019 = 2 minor
  - 2021 = 0 minor
  - 2024 = 1 minor
- Three consecutive audits with Level 1 compliance!
- Achieved a 3-month audit consistency extension 👍

## Other Success Stories

### ■ Positive Customer feedback during audits

- Clear evidence of established and mature Quality Systems in place
- Clean and well-maintained facility
- Extensive monitoring and control of key areas
- Detailed and thorough documentation and processes
- Strong staff retention that contributed to the preservation of institutional knowledge and an experienced workforce

### **Don't waste the opportunity of a crisis**

They are great opportunities to change behaviours and to improve

We debrief post crisis to see what we can learn

Its not as difficult as it sounds, its actually quite simple!

**Don't over complicate it**

**Don't over think it**

**But don't under think it either!!**

# Thank You