

# Microbial Challenges when Sourcing Herbal Substances

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# Herbs in a Bottle

- Herbal medicines for practitioners
- Nutritional supplements including botanicals, vitamins and minerals
- Sports nutrition products
- Traditional Herbal Registration (THR) products



# Herbs in a Bottle

- Manufacturers Licence (MIA 37212)
- Quality Management System in place
- Good Manufacturing Practice (GMP)
- Product types:
  - Fluid extracts and tinctures
  - Bulk herbs and powders
  - Capsules
  - Tablets
  - Powder blends
  - Liquid blends



# Herbs in a Bottle

- Herbal Raw Material
  - Dried Herbs – microbiological problem
  - Herbal Extracts – not a microbiological problem



# Herbs in a Bottle

- Herbal Raw Material Historical Problems
  - Historically failures of batches once tested on site
  - Difficult to return failed batches to suppliers
  - Build up of useless stock
  - Expensive

# Herbs in a Bottle

- Purchasing Process for Herbal Raw Material
  - Request pre purchase sample from the supplier
  - Test pre purchase sample for ID (visual), Micro, Moisture and Ash
  - Approve/Reject sample
  - If Approved buy in bulk
  - Test bulk for ID (visual and HPTLC), Moisture and Ash
  - Further deliveries of same batch will be tested for micro

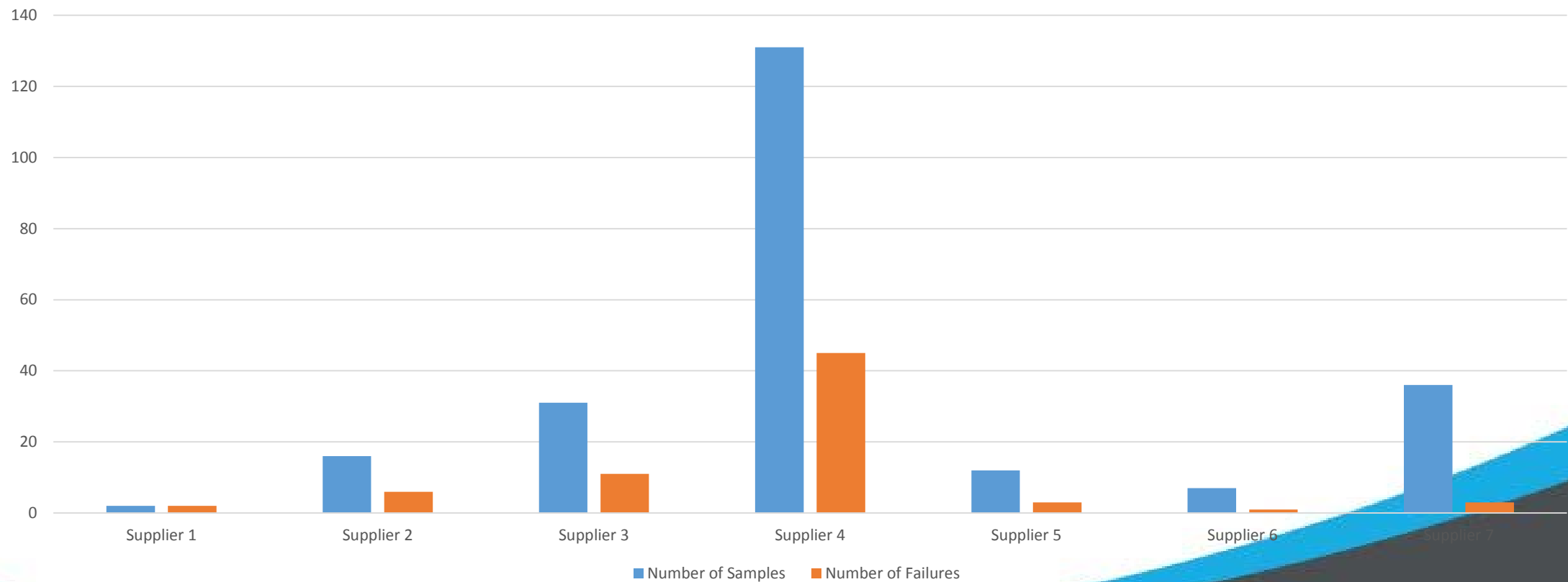
# Herbs in a Bottle

- Herbal Specification (Ph. Eur 5.1.8 C)

Test	Acceptance Criteria
TAMC	<500,000
TYMC	<50,000
Bile tolerant gram-negative bacteria	<10,000
E. coli	Absent in 1g
Salmonella	Absent in 25g

# Herbs in a Bottle

Pre Purchase Sample Micro 2015





# Microbiological Failures

Material	TVC <500,000	Enterobac. <10,000	Yeast <50,000	Mould <50,000	E coli Not Detected
Althaea off. rad	4,400,000	<20	<20	<20	ND
Althaea off. rad	5,600,000	840,000	<20	7,800	ND
Crataegus laev	720,000	660,000	<20	380	650
Cynara scolymus	5,200,000	2,440,000	<20	240	1,100
Echinacea purp.	2,000,000	720,000	<20	<20	ND
Salvia off.	840,000	780,000	<20	7,200	ND
Silybum mar	7,200,000	6,000,000	<20	24,000	5,700
Ocimum sanctum	5,600,000	1,100,000	<20	60,000	1,500

# Herbs in a Bottle

- Current system
  - High failure rate 25%-66%
  - Slow, 12+ week lead time on herbs
  - High levels of out of stock
  - Customer dissatisfaction
  - Risk assessments on some out of specification herbs - Safety

# Herbs in a Bottle

- OOS Risk Assessment

- Product type i.e. capacity for micro proliferation in the finished product
- Practitioner/customer use of the material i.e. volume consumed
- Vulnerable groups: the elderly, children, disease state of patient/consumer
- Environmental factors for the growth of herb
- Food limits
- THR – No risk assessment, registered limits

# Herbs in a Bottle

- The future
  - Working on an agreed buying specification with herb suppliers
  - Audit
  - Supplier partnerships/contract
  - Larger stock holding of herbs (6 months)
  - Larger minimum stock levels (3 months)
  - Improved customer service level whilst maintaining quality
  - Trend analysis
  - Education of suppliers and customers

# Herbs in a Bottle

- Conclusion

- Microbiological contamination is a problem when buying dried herbs
- Testing is critical to maintain safe products
- Build quality in to the supply chain to minimise failures