

VALIDATING BENEFITS OF PRODUCTS

DR PAUL DAVIS
DIRECTOR OF OPERATIONS & RESEARCH
TRINITY BIOACTIVES LTD.
WELLINGTON

March 21, 2014



- NATURAL PRODUCTS
- NUTRICEUTICALS
- COSMECEUTICALS
- FUNCTIONAL FOODS

HEALTH CLAIMS

HEALTH BENEFITS

HUMAN

ANIMAL

VALIDATING PRODUCTS

TWO GENERAL APPROACHES - COMPOSITIONAL
- ACTIVITY

ALSO

- STABILITY
- BIOAVAILABILITY

NATURAL PRODUCTS

SPECIFIC CONSIDERATIONS

VARIABILITY

- SEASONALITY (Climate)
- ENVIRONMENT
- PROCESSING (Extraction methods)
- GENETICS
- FEEDING, NUTRIENTS

NATURAL PRODUCTS

CONSEQUENCES:

VARIABILITY IN PRODUCT COMPOSITION

THEREFORE

IN ACTIVITY

(EMU OIL)

VALIDATION

RELEVANT TO

- 1) USE OF PRODUCT
- 2) APPLICATION METHOD
- 3) BENEFIT

TESTING METHODOLOGY

RELEVANT TO

- 1) APPLICATION OF PRODUCT
- 2) CLAIMED BENEFITS

TESTING

Natural Products

- Variabilities

**Genetic
Location**

Environmental (Temperature, Light, Soil, Marine, UV)

Testing different batches

COSTS

Costings not high

Testing must be

- recognised
- appropriate
- well-designed

Recognise advantages & limitations of methods

MARKETING

- ❖ Use methods for marketing
- ❖ Accurate interpretation
- ❖ Costs minimised – coupling of validation and marketing

REGULATORY REQUIREMENTS

Some jurisdictions - compulsory regulatory requirements

- different countries
- different uses, applications

REGULATORY REQUIREMENTS

- ❖ Testing, validation may not need to be GLP
- ❖ Nutraceuticals, natural products
- ❖ Depends on regulations of specific jurisdictions
- ❖ Cost savings

As well as for VALIDATION

Testing can be for

- comparison with competitors' products
- mechanisms of activity
- investigating role of constituents
- developing or changing processing

HIERARCHY OF TESTING

- In vitro
- In vivo
- Human or animal trials

EXAMPLES

1. Skin health
 - Validated activity
 - Sales increased
 - Competitors take notice
2. Anti-inflammatory
 - Testing on several occasions
 - Reliable data
 - Various processing & storage conditions
 - Making more active product

HIERARCHY OF TESTING

- In vitro
- In vivo
- Human or animal clinical trials

Thank you



