

VALIDATING BENEFITS OF PRODUCTS

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- 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



