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Managing Quality of Your Herbal Raw Materials



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- Why manage quality of herbal raw materials?
- Deciding what parameters to control?
- How much Quality Control is enough?
- What can happen if we don't have sufficient controls in place?
- The cost of quality
- Quality Control and the NZ Natural Products Bill



Value through expertise

In this presentation we'll be discussing the very need to manage quality of your herbal raw materials. Why would your business bother? What should you include in your Quality Control (QC) regime – how much is enough – can we overbake the QC pie. How much is too little?

Importantly, what can happen in and to your business if adequate QC is not part of your business routine and structure. In considering what QC is appropriate, how do you measure the cost to your business since QC is often a 'sunk cost', not measured in detail and seldom understood.

Finally, the presentation will touch on the New Zealand Ministry of Health Natural and Supplementary Products Bill that was under debate at the time this presentation was delivered to the Natural Products New Zealand member base in August 2016. We'll take a brief look at the impact of the Bill on QC, and the impact of QC on the Bill.



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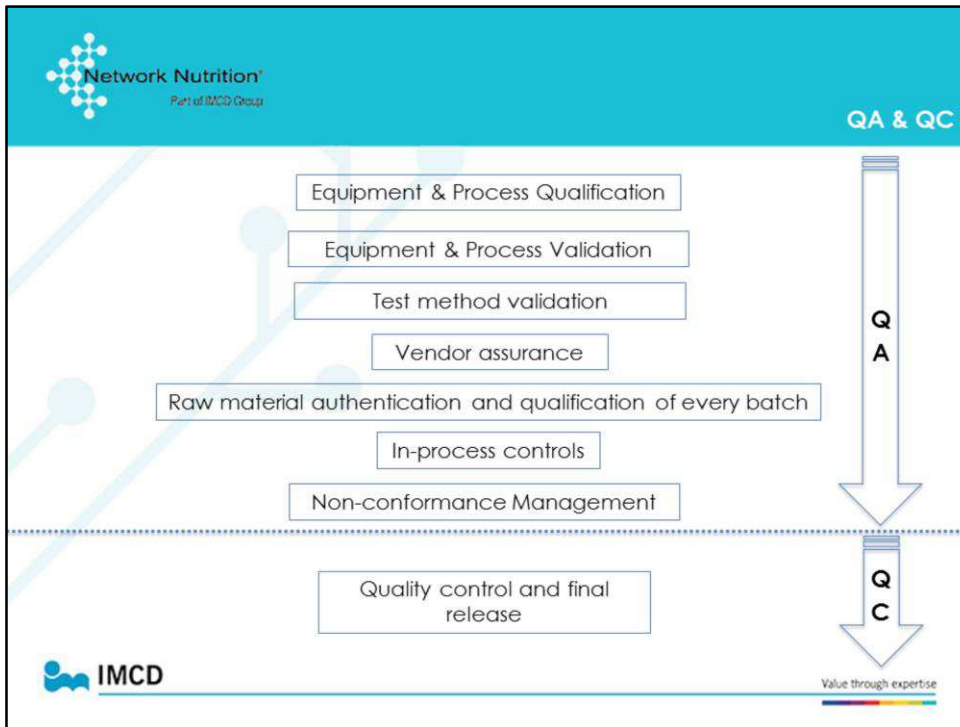
Why, Oh Why!?

- Warrant safety of finished products
- Deliver a consistent effect on health
 - Protect your business!
- Make your products defensible from attack
- Preserve the integrity of your Brand
- Contribute to your marketing message



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QC is important to warrant the safety of your finished products to both to your business and to the end-user. Consider it like an extra layer of business insurance. A defence mechanism to help protect your products from scrutiny by consumers, media or competitors. Strong QC platforms can assist your finished product to deliver the intended therapeutic outcomes batch after batch, and will allow you to monitor quality trends that might have an impact on the efficacy of your product. Being in a position to support your products with a well-built QC platform is also useful for the marketing of your product – allowing you to make standardised claims and point to specific quality differentiators that set your product apart from the competition.



It's important to recognise the difference between Quality Assurance (QA) and Quality Control (QC). Quality Assurance is essentially the systems and processes put in place by a business to deliver a known product outcome (aka to meet a pre-set specification). Quality Control involves the checking of the product usually by way of a series of tests, in order to confirm that the pre-set specification has indeed been met. These two core aspects of any Quality Management system operate independently of one another whilst also being inter-dependent on many levels.

What!?

1. IDENTITY
2. POTENCY
3. PURITY

Deciding what to include in your quality control programme can be simplified into three main areas to consider.... 1) Identity involves identification, authentication and adulteration detection. 2) Potency is relevant particularly when making standardised claims but also when not. 3) Purity looks as things like microbiology, contaminants, moisture, heavy metals, aflatoxins and biological or phyto-chemical impurities that might naturally occur in the raw herb though would be undesirable in a medicinal herb extract.

How Much!?



- Assess the risk
- Know the source
- Make the call
- Observe the trends

Determining the level of Quality management to overlay upon your product range is a matter for critical assessment by your experienced Quality, Technical & Regulatory teams. Pragmatism is the order of the day here to ensure your business locates the right balance of appropriate Quality management. At some point, the business needs to decide what level of Quality management is appropriate and be ready to back itself with sound justifications. Different businesses assume differing risk profiles, and so approaches to Quality management will also differ from one business to another.



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What If!?

- Adulteration
- Contamination
- Sub-potency



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What if we don't manage control of herbal materials? What could possibly go wrong!? Just about everything! We're dealing with products borne out of Mother Nature.....

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Alibaba.com
Global trade starts here.™

 <p>Bilberry extract powder 25% Anthocyanin / cyanidin US \$1-200 MOQ: 1 Kilogram/Kilogr...</p> <p>Contact Supplier</p>	 <p>Manufacturer Supply Bilberry Extract with Good ... US \$12-70 MOQ: 1 Kilogram/Kilogr...</p> <p>Contact Supplier</p>
 <p>Bilberry Extract at factory price 001 Get Latest Price MOQ: 10 Ton/Tons</p> <p>Contact Supplier</p>	 <p>ISO/GMP factory supply Bilberry Extract powder ... US \$10-100 MOQ: 1 Kilogram/Kilogr...</p> <p>Contact Supplier</p>

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Huge variations exist in the world of herbal ingredients – products that might look the same at a glance can differ significantly. Take this example of Bilberry extract available on popular e-commerce website Alibaba.com – with genuine Bilberry extract typically commanding around NZD800-900/kg, it could be interesting to see what you can buy on Alibaba for a dollar!

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Pharmacopeial HPLC identification methods are not sufficient to detect adulterations in commercial bilberry (*Vaccinium myrtillus*) extracts. Anthocyanin profile provides additional clues

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Network Nutrition, through its program for adulteration detection called NPAD, developed a new and simple method for detecting adulteration of Bilberry. That method was peer reviewed and published in *Fitoterapia* at the end of 2014.



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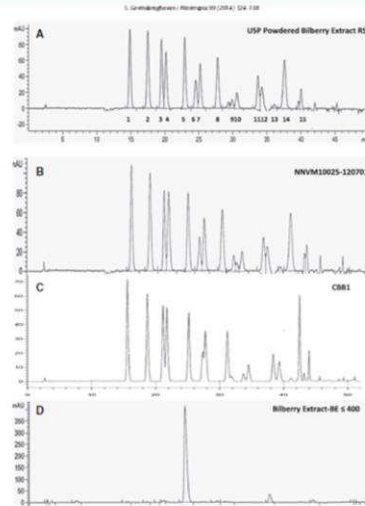
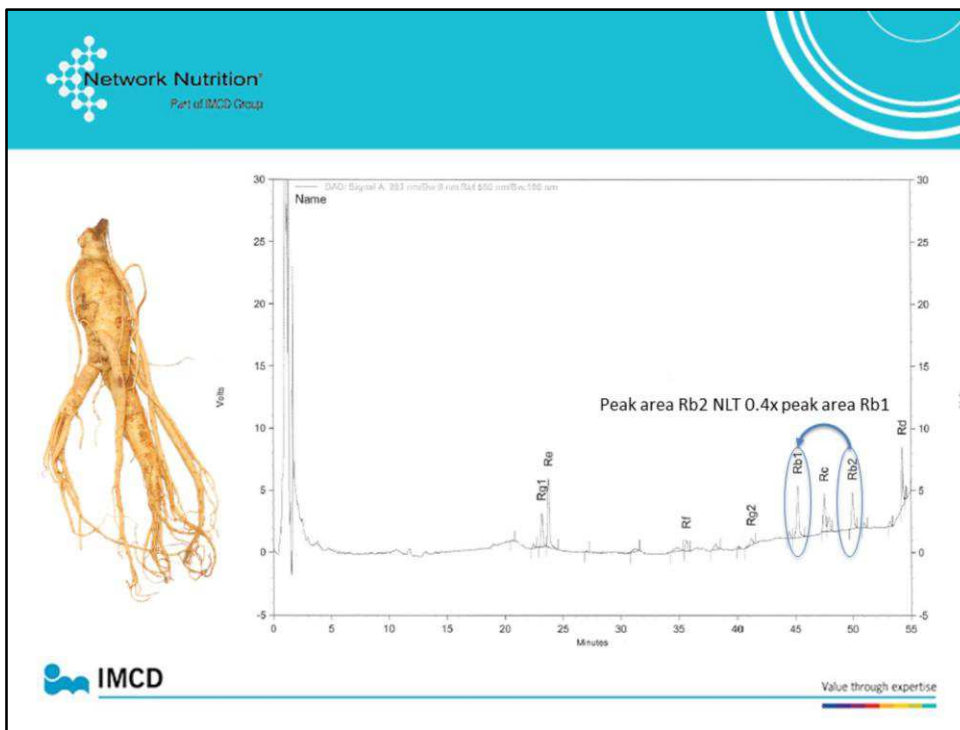


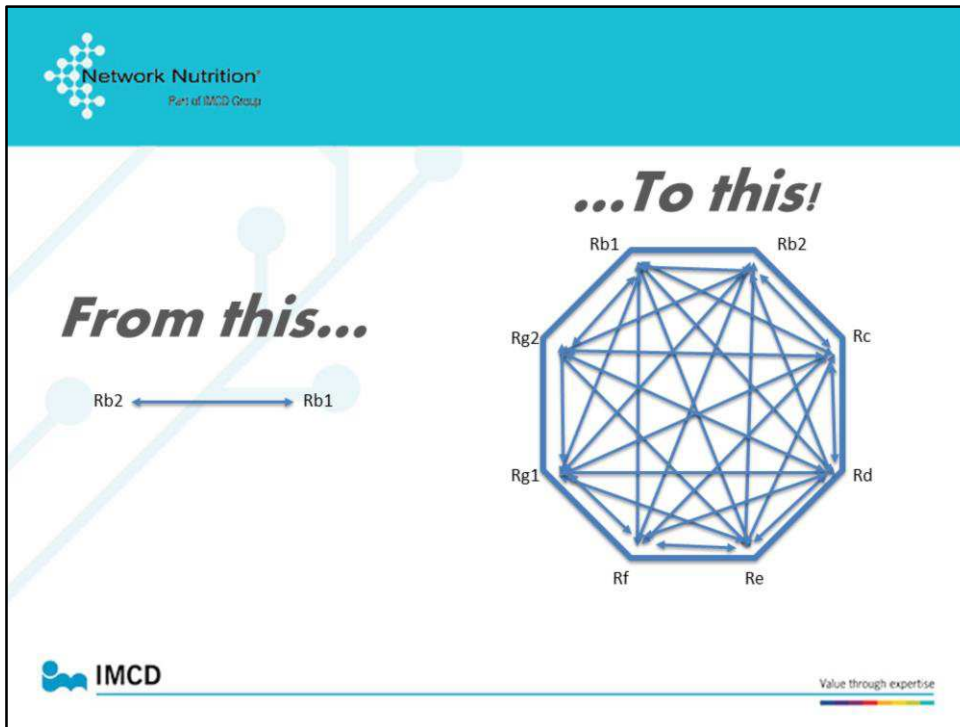
Fig. 5. NPAD, GC-MS and HPLC-MS chromatograms of bilberry extracts. The assignment of peak numbers is given in Table 2.

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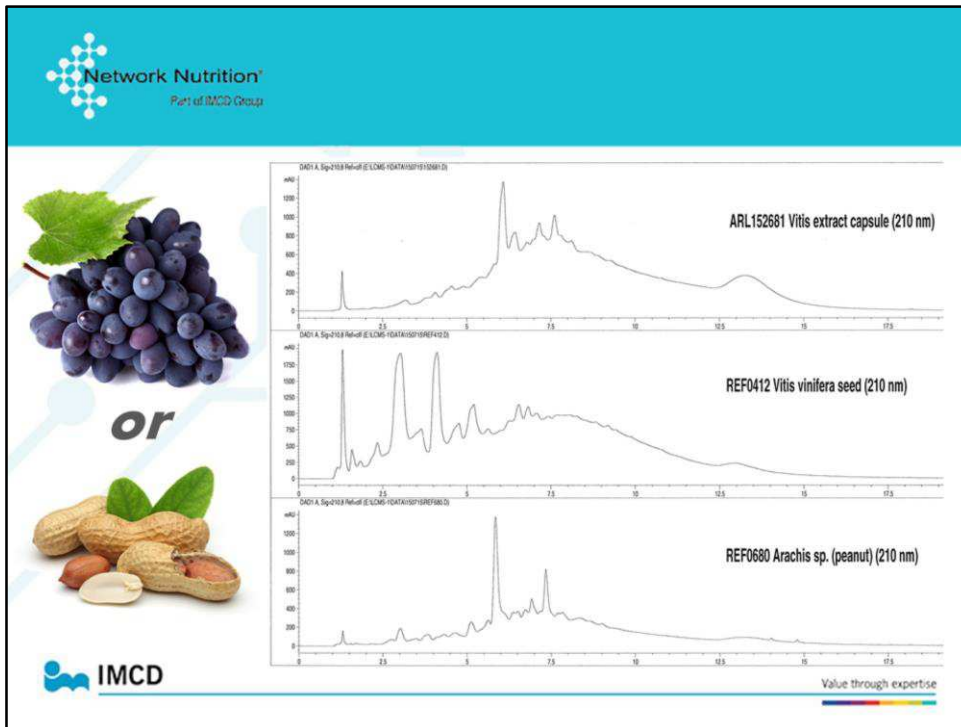
The NPAD method exposed many new and sophisticated ways to make a variety of low-cost ingredients look like Bilberry to the untrained eye. In the chromatograms above A = USP reference, B = NN Bilberry extract (code: NNVM10025), C & D = Bilberry extract from China



Korean Ginseng has been another widespread target for adulteration, due to its global popularity as a tonic, adaptogen, for energy, stamina and sexual function. Methods commonly used by industry instruct the analyst to make a comparison of values of one particular ginsenoside to another. This has long been deemed insufficient to detect recent advances in adulteration techniques.



Recent NPAD work by the Network Nutrition scientific team points to a more causal relationship between 8 ginsenosides. This newly developed NPAD pattern provides an impervious identification method without the need for additional testing. The analyst can make a critical assessment of the data available from existing HPLC assay work in order to see if they've been supplied a genuine extract, or not.



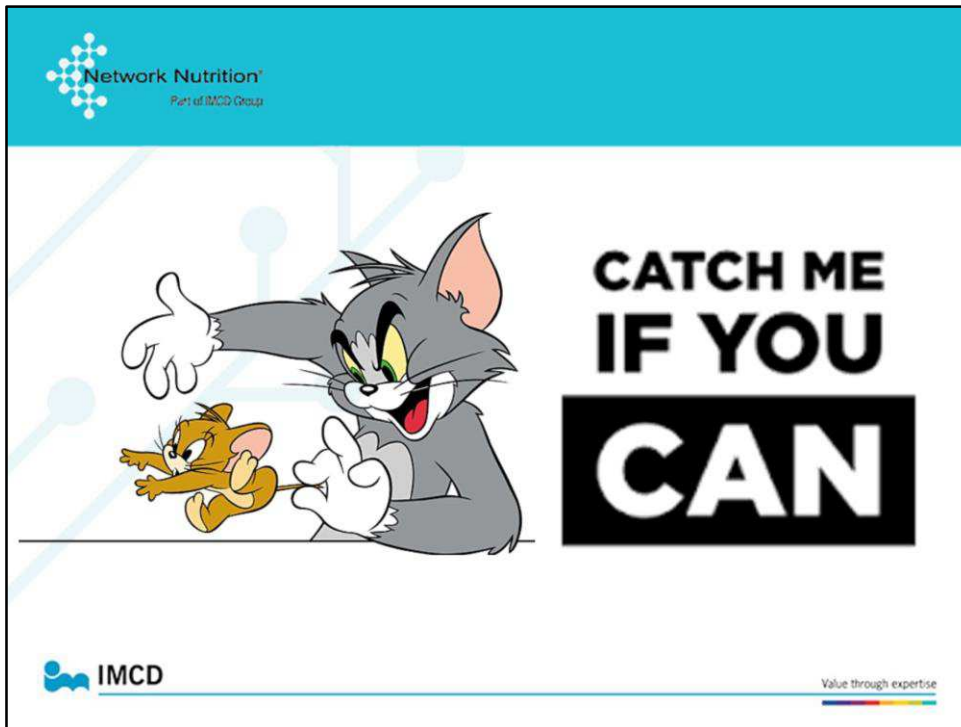
Other interesting research work underway with NPAD is the contamination of Grapeseed extract with Peanut skin. These chromatograms show the comparison of an Australian Listed medicine claiming to contain Grapeseed vs. an authenticated Grapeseed material vs. an authenticated Peanut skin material. Can you spot the difference?



Is herbal adulteration really a problem?

- | | | |
|-------------------|------------------|----------------------|
| 1. Ginkgo | 8. Saw Palmetto | 15. Valerian |
| 2. Korean Ginseng | 9. Echinacea | 16. Grapefruit Seed |
| 3. Bilberry | 10. Withania | 17. Siberian Ginseng |
| 4. Milk Thistle | 11. Cinnamon | 18. Goldenseal |
| 5. Red Clover | 12. Black Cohosh | 19. Pomegranate |
| 6. Cranberry | 13. Skullcap | 20. Acerola |
| 7. Horsetail | 14. Turmeric | 21. Guarana |

There are more than one or two herbs that have, over time, become targets for adulteration. A herb tends to become a target once it achieves mainstream popularity and is prone to significant market pressure to reduce cost-in-use.



So its the ethical element of industry against the 'Underbelly' in a perpetual game of cat-and-mouse.



As well as keeping your eye on unscrupulous practices which have become so commonplace, as important is the screening for inherent or environmental contaminants – these can include pesticide residuals, heavy metals, PAH's, PA's, aflatoxins, solvent residuals, and many more.



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- Staff
- Equipment
- Training (ongoing)
- Access to literature
- Procedures
- Consumables
- Validation
- Outsource?



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If you consider the indirect cost implications of low or no quality control when you're in damage control or crisis mode as a result of a quality matter, the seemingly high cost of managing quality becomes more-and-more an attractive option for many businesses.

Here are some important factors to consider when assembling your Quality management program.

Businesses should also consider the viability of outsourcing some or all tests. This can sometimes prove to be a more cost effective means of achieving the same Quality management outcomes.



With the seemingly imminent legislation of the Natural & Supplementary Products Bill by New Zealand's Ministry of Health, consideration should be given by businesses as to the impact that the proposed Manufacturing Code of Practice might have on the need for a well designed Quality Management System, incorporating Quality Control of inbound herbal materials.



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Thank You!

Questions!?



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