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附件：課程資訊1份 (SPACE、ISO、workshops008638.pdf)

主旨：檢送馬來西亞廠房國際ISO Workshop標準培訓課程資訊，
請查照。

說明：

- 一、本院執行衛生福利部111年「新南向傳統醫學人員交流合作計畫」，獲知馬來西亞南方大學學院提供國際標準MS ISO/IEC17025:2017線上培訓課程，以供我國有興趣前往設廠之中藥廠規劃參訓，授課語言以英文為主（課程資訊如附件）。
- 二、若有參訓需求可逕向該校洽詢（E-mail：space@sc.edu.my 或wclui@sc.edu.my）。

正本：臺灣中藥工業同業公會、中華民國中藥商業同業公會全國聯合會、英橋企業股份有限公司龍德製藥廠、仙豐股份有限公司蘇澳製藥廠、肝王製藥股份有限公司、順天堂藥廠股份有限公司新店廠、元一生技製藥股份有限公司、華僑製藥有限公司、廣東製藥股份有限公司、國科生技製藥股份有限公司、中天生物科技股份有限公司龍潭廠、深浦藥品股份有限公司龍潭廠、科達製藥股份有限公司、京都念慈菴藥廠股份有限公司龜山廠、勸奉堂製藥股份有限公司桃園廠、腦得生製藥有限公司、宏星製藥廠股份有限公司、勝昌製藥廠股份有限公司中壢廠、昕泰生技製藥股份有限公司、三才堂製藥廠有限公司、人壽製藥廠股份有限公司、順天堂藥廠股份有限公司台中廠、鄭杏泰生物科技股份有限公司台中廠、明通化學製藥股份有限公司第二廠、得力興生技藥業股份有限公司、井田生化科技股份有限公司、大濟製藥廠股份有限公司、順然藥品股份有限公司南投廠、富田製藥廠股份有限公司、復旦製藥股份有限公司、康百氏製藥股份有限公司、吉立製藥股份有限公司、愛康製藥廠股份有限公司、正光製藥有限公司、福安科技製藥股份有限



公司、壽山生物科技製藥廠、順瑛堂生物科技製藥股份有限公司、晉安製藥股份有限公司、德山製藥股份有限公司、信宏科技製藥股份有限公司、雲南製藥股份有限公司、太和堂製藥股份有限公司、廣泉堂製藥化學有限公司、艾力特生技製藥股份有限公司將軍廠、華昌製藥生化科技股份有限公司、東陽製藥股份有限公司、仙鹿製藥股份有限公司、天一藥廠股份有限公司、優之堡生技製藥股份有限公司新營廠、仙台藥品工業股份有限公司、炳翰製藥廠股份有限公司、港香蘭藥廠股份有限公司、生春堂製藥工業股份有限公司、得生製藥股份有限公司、臺灣三帆製藥科技股份有限公司、愛生製藥廠有限公司、新喜國際企業股份有限公司、豐生製藥生物科技股份有限公司、全生製藥股份有限公司、立安生物科技製藥股份有限公司、大維生化製藥國際有限公司、德和製藥廠、莊春仁生物科技製藥有限公司、三友生技醫藥股份有限公司製藥廠、聚安堂藥廠股份有限公司、立康生物科技股份有限公司、港香蘭應用生技股份有限公司、領先奈米製藥生技股份有限公司台南廠、三泰製藥廠有限公司、北京同仁堂生物科技股份有限公司高雄廠、莊松榮製藥廠有限公司、旺霖製藥工業有限公司、匯宏製藥股份有限公司、南美製藥股份有限公司、台灣順安生物科技製藥有限公司大發廠、東發生物科技製藥股份有限公司、漢聖製藥科技股份有限公司、莊松榮製藥廠有限公司里港分廠、輝陽藥品股份有限公司、天明製藥股份有限公司、喬本生醫股份有限公司、漁人製藥股份有限公司、金牌一條根生物科技有限公司、裕益製藥有限公司

副本：衛生福利部(含附件)、本院計畫主持人賴榮年中醫副院長

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**School of Professional and Continuing Education (SPACE)
Southern University College**

Date: 27/5/2022

| No | Workshop Name | Introduction | Learning outcome | Training Hours |
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| 1 | Estimation of the Measurement Uncertainty for ICP-MS Method in fulfilment of MS ISO/IEC17025:2017 (Online Mode) | Workshop Course Contents: 1. Introduction to Method Validation 2. Guide to the Expression of Uncertainty in Measurement (GUM) 3. The Process of Measurement Uncertainty Estimation (GUM Approach) 4. Estimation of the Uncertainty of the Measurement Results using ICP-MS | At the end of the course, the participants should be able: • To establish a proper procedure in estimation of MU for ICP-MS method; • To execute step-by-step calculation of MU for volume, sampling, purity, calibration, recovery, repeatability uncertainties. | 16 Hours (2 Days, 9am - 5pm) |
| 2 | MS ISO/IEC17025:2017 Measurement Uncertainty & Risk Management (Online Mode) | Workshop Course Contents: 1. Guide to the Expression of Uncertainty in Measurement (GUM) 2. Estimation of the Uncertainty of the Measurement Results 3. Impacts of the MS ISO/IEC 17025:2017 Revision 4. Lab QC Based on Risk Management 5. Quality Tools for Risk Assessment | This course is recommended for chemists and technologists who are working in a MS ISO/IEC17025:2017 accredited laboratory. At the end of the course, the participants should be able: • To establish proper procedure in estimation of MU for a test method; • To execute step-by-step calculation of MU for volume, sampling, purity, calibration, recovery, repeatability uncertainties; • To implement risk assessment in measurement; • To utilise QC tools for risk assessment. | 16 Hours (2 Days, 9am - 5pm) |

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| 3 | <p>Understanding the Elements of MS ISO/IEC 17025:2017 – Measurement Risks & Decision Rules (Online Mode)</p> | <p>Workshop Course Contents:</p> <ol style="list-style-type: none"> 1. Introduction to Quality Management Systems 2. Introduction to MS ISO/IEC 17025:2017 3. MS ISO/IEC 17025:2017 Major Changes 4. Impacts of the MS ISO/IEC 17025:2017 Revision 5. Lab QC Based on Measurement Risks 6. Measuring Risk 7. Implementing the Decision Rules | <p>At the end of the course, the participants should be able:</p> <ul style="list-style-type: none"> • To understand the impacts of newly revised version of MS ISO/IEC17025; • To do gap analysis on existing laboratory quality policies; • To determine measurement risks from equipment and calibration; • To implement decision rules in laboratory results reporting. | <p>16 Hours (2 Days, 9am - 5pm)</p> |
| 4 | <p>Statistical Methods for Method Validation (Online Mode)</p> | <p>Workshop Course Contents:</p> <ol style="list-style-type: none"> 1. Part 0: Introduction to Method Validation 2. Part A: Descriptive Statistics 3. Part B: Outlier Tests 4. Part C: Significant Testing 5. Part D: Regression Analysis 6. Part E: Control Chart 7. Part F: ANOVA | <p>At the end of the course, the participants should be able:</p> <ul style="list-style-type: none"> • To recognise the different probability distributions: normal, rectangular and triangular; • To identify the outliers from a set of analytical data by statistical analysis; • To carry out significance testing for differences, if any, between two methods, techniques or analysts' performances for method validation; • To set up simple laboratory quality assurance practises based on control charting; • To interpret data output from MS Excel data analysis software applications | <p>16 Hours (2 Days, 9am - 5pm)</p> |
| 5 | <p>Good Laboratory Practices - Skills & Techniques</p> | <ol style="list-style-type: none"> 1. Basic Tools and Operations of Laboratory Experiments <ol style="list-style-type: none"> a) Analytical balances b) Glassware c) Pipettes d) pH Meter e) Refrigerator, Freezer & Centrifuge f) Maintenance programme g) Preparation of standard solution 2. Workplace Safety 3. Data Collection and Simple Statistics 4. Validation for Instrumental Analysis | <p>At the end of the course, the participants should be able:</p> <ul style="list-style-type: none"> • To understand instrument and glassware uncertainty; • To calculate and prepare standard solutions; • To establish lab safety procedure and waste management; • To distinguish the significant figures in calculations and instrumentation; • To carry out performance checks on simple lab equipment | <p>16 Hours (2 Days, 9am - 5pm)</p> |

Trainer:

Prof ChM Dr **Teh Geok Bee** FASc

- Fellow, Academy of Sciences Malaysia 2021
- Fellow, Institut Kimia Malaysia 2015
- Member, Organization for Women in Science for the Developing World
- President / CEO, Southern University College

G. B. Teh is the President and Chief Executive Officer of Southern University College. G. B. Teh earned her MPhil and PhD degrees in the field of Chemistry at University of Cambridge, United Kingdom, and her 1 st Class Honours degree in Applied Sciences at the National University of Malaysia. She is a UNESCO-TWAS Associateship Scheme recipient for research attachment at Jawaharlal Nehru Centre for Advanced Scientific Research, Bangalore, India and had numerous research attachments at MacDiarmid Institute for Advanced Materials and Nanotechnology Victoria University of Wellington, New Zealand under the sponsorship of New Zealand ISAT Linkages Fund.

G. B. Teh's research interests are primarily in the areas of synthesis and structural elucidation of functional nano magnetic oxide and application of nanoparticles in structural engineering. G. B. Teh has been a lecturer for over 20 years and has taught at undergraduate and postgraduate levels at two other private institutions of higher learning. Being a MQA panel assessor, she was instrumental in setting up many master's and PhD programmes.

Contact us

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