SHORT COURSE

THE THEORY OF SAMPLING APPLIES IN PHARMACEUTICAL MANUFACTURING

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MISTY HILLS CONFERENCE CENTRE
MULDERSDRIFT, JOHANNESBURG
SOUTH AFRICA

SAIMM
THE SOUTHERN AFRICAN INSTITUTE OF MINING AND METALLURGY

Course provider: Dr. Rodolfo Romañach, professor of Chemistry at the University of Puerto Rico –Mayagüez Campus, and Chair of the National Institute for Pharmaceutical Technology and Education Faculty (NIPTE.org).

The Process Analytical Technology (PAT) guidance, issued by the US FDA in 2004, describes an important new strategy to improve pharmaceutical manufacturing[1]. This strategy sparked many other important efforts to bring much needed higher quality products to patients.

During the past 10 years the Theory of Sampling (TOS) has been extensively applied in pharmaceutical PAT applications. This has resulted in a new perspective of pharmaceutical processes and PAT methods through the principles of TOS[2-5].

This short course is intended to further continued pharmaceutical interest in TOS. Several pharmaceutical applications will be discussed as important key principles and sampling unit operations are reviewed.

Learning Objectives:

At the end of this course participants will be able to:

- Explain the motivations for Process Analytical Technology
- Define and explain relevant sampling errors associated with PAT sensor technology.
- Explain how the Theory of Sampling applies to PAT processes.
- Explain how Lot Dimensionality Transformation (LDT) may occur in a pharmaceutical process, and be able describe the significant its benefits

Course Outline:

Topic	Time (min)
Introduction -	15
PAT Guidance	20
PAT Benefits	20
Effect of Heterogeneity on PAT and Near Infrared Spectroscopic methods – Defining a Sampling Error. Fundamental Sampling Principle. Representative Sampling.	30
Composite Sampling in near infrared and Raman spectroscopic methods	20
PAT and Continuous Manufacturing	20
Lot Dimensionality Transformation in Pharmaceutical Applications. MPE and Repeatability in CM.	30

About the Presenter

Dr. Rodolfo Romañach is focused on developing analytical methods for monitoring of pharmaceutical manufacturing processes in situ and providing this information to engineers for process optimization. His goal is to embed Quality Control in the production environment to provide real time measurements that may be used to control and improve manufacturing processes. This systematic approach is termed Process Analytical Technology (PAT).

All Quality Control depends on *how* samples are obtained from a process. Dr. Romanach has studied the Theory of Sampling and is a prime mover in adapting its principles to pharmaceutical processes.

He is currently professor of Chemistry at the University of Puerto Rico –Mayagüez Campus, and is Chair of the National Institute for Pharmaceutical Technology and Education Faculty (NIPTE.org).

References (course documentation):

1. U.S. Department of Health and Human Services, F.D.A., Guidance for Industry - PAT A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance. 2004. pp. 1-19.
2. Esbensen, K.H. and Romañach, R.J. A Framework for Representative Sampling for NIR Analysis–Theory of Sampling (TOS). *Handbook of Near-Infrared Analysis*, 4th ed. Ciurczak, E.W., Igne, B., Workman, J., Burns, and D.B. Eds. Taylor & Francis Group: Boca Raton, Fla, 2021.
3. Romañach, R., Joubert Castro, A., and Esbensen, K., WHAT are sampling errors—and WHAT can we do about them? Part 1. *Spectroscopy Europe* 2021, 33 (2), 7.
4. Esbensen, K.H., Romañach, R.J., and Román-Ospino, A.D. Chapter 4 - Theory of Sampling (TOS): A Necessary and Sufficient Guarantee for Reliable Multivariate Data Analysis in Pharmaceutical Manufacturing. *Multivariate Analysis in the Pharmaceutical Industry*, Ferreira, A.P., Menezes, J.C., and Tobyn, M. Eds. Academic Press: London, United Kingdom, 2018. pp. 53-91.
5. Sánchez-Paternina, A., Sierra-Vega, N.O., Cárdenas, V., Méndez, R., Esbensen, K.H., and Romañach, R.J. Variographic analysis: A new methodology for quality assurance of pharmaceutical blending processes. *Computers & Chemical Engineering* 2019, 124, pp. 109-123.

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