# 連続生産（CM）研究会（仮称）主催
# ミニ講演会：Martin Warman氏を囲んで

とき：7月13日（金）　10時30分～12時
ところ：品川インターシティ、会議室5

## プログラム

1. 連続生産の動向と連続生産研究会設立について
2. Martin Warman氏のミニ講演
3. 連続生産に関する討論会（マーティン氏を囲んで）

# 背景

1.標準処方研究フォーラム,PBP2018; IFPAC2018

2.世界のコンソーシアム; by Douglas B. Hawsner, Rutgers Univ. in 2018 ISPE

- C-SOAP(2006-, Rutgers Univ. etc.)
- Novartis-MIT Center (2007-)
- CPAC(1984-), CMAC(2011-)
- SSPC(2013-), RCPE(2008-)
- PSSRC(2018-, Univ. of Ghent)

3.PMDAの動き（AMED研究、松田班）

4.日本のコンソーシアム；NPTE:グローバル化

# Douglas B. Hawsner, Rutgers Univ. in 2018 ISPE

## NPTE

- The New Pharmaceutical Technology and Engineering Institute
- Established in 2003
- Focus – broad, particle technology
- Joint industry academia group, industry driven


**December workshop planned in collaboration with C-SOPS*

11th World Meeting
on Pharmaceutics, Biopharmaceutics and
Pharmaceutical Technology
19 March to 22 March 2018 | Granada, Spain

# Continuous manufacturing in Japan:
## Our challenges in characterizing pharmaceutical processes including continuous granulation and tableting

**Hirofumi Takeuchi, Prof.**

**Gifu Pharmaceutical University, Japan**

**Committee members of SFR group in PPD, The Society of Powder Technology, Japan**

# Standard Formulation Research (SFR) Group

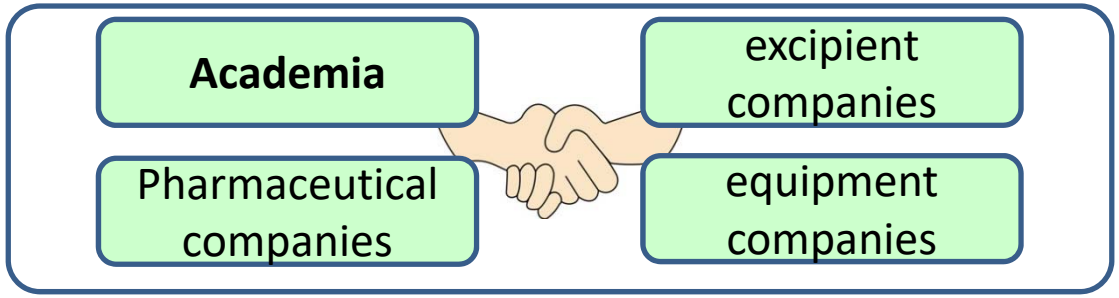


- Needs for pharmaceutical companies:
  How to evaluate the new equipment for granulation?
- Needs for pharmaceutical equipment and excipient companies:
  What is the actual need of pharmaceutical companies to equipments and excipients?

⇒It is very easy to do it, if the common test formulation is available.

**Standard Formulation Research Group (set up in 1985)**

- Questionnaire was the first step to know the knowledge about **standard formulation** in several pharmaceutical companies and set up the study policy.
- The members have started **granulation experiment** together at the test rooms of the members by using the **standard formulation**.
- The results were reported in the annual **SFR Forum** to share the knowledge in this field.



# Projects studied in SFG (3)



Research project was connected to ICH Q trio: process analysis, design space etc. (2008 – )

3-1) Study on direct compression (Scale up on mixing process: Degree of lubrication)

Evaluation method: Flowability, Particle angle of internal friction,
Powder transport properties by vibration,
Pressure transmission rate,
Effective cascade movement distance,
NRI/Raman imaging etc.

Data analysis: Design of experiments (DOE) and DataNESIA

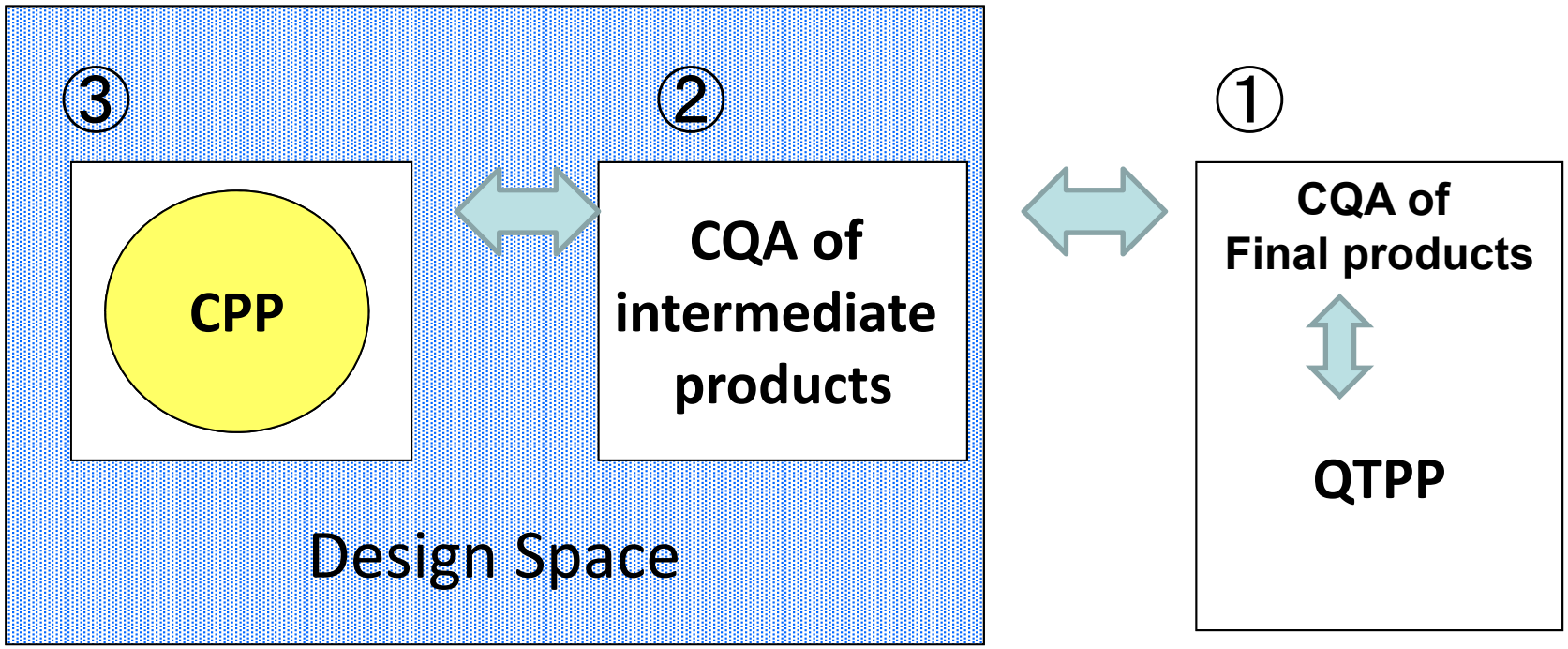
3-2) Study on Degree of Granulation

Evaluation method: Particle angle of internal friction,
Powder rheometer,
X-ray micro computed tomography,

Data analysis: Practical linear process analysis and Practical non-linear analysis

3-3) Study on continuous manufacturing (2015 – )

# Design Space,
# Critical Process Parameter (CPP),
# Critical Quality Attribute (CQA),
# Quality Target Product Profile (QTPP)





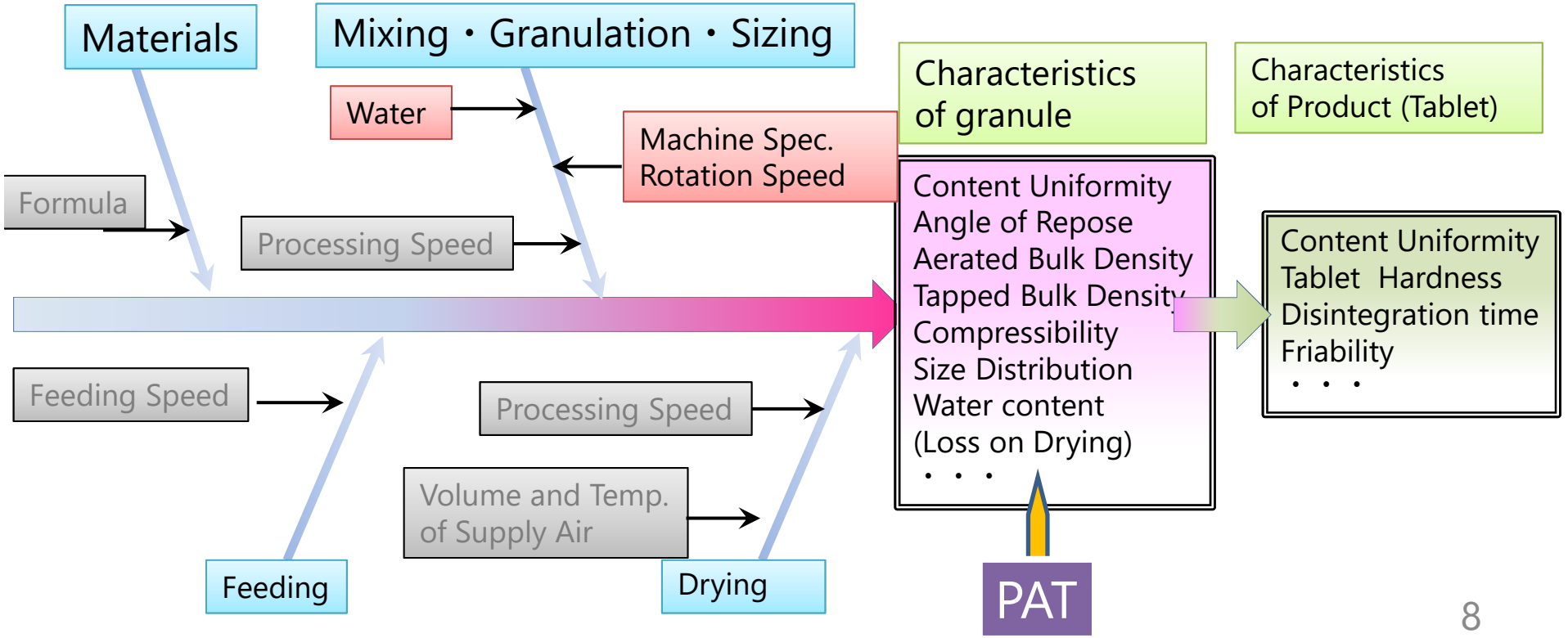

檜山行雄ら、「ICHQ8と企業戦略」，日本PDA技術教育委員会講演資料（2008）

2nd and 3rd year

# Relationship between CPP and CQA

To understand continuous granulation more, several types of model experimental with standard formulation were carried out as follows;

- ✓ Process Control with PAT tools on long time operation
- ✓ Content uniformity (resultant granules and tablet with low content)
- ✓ Extraction of CPP highly reflected on CQA, and construction of design space



# AMED sponsored study group

## Research into Quality Assurance of Pharmaceutical Continuous Manufacturing

It was started on August 15th , 2016.,
chaired by Dr. Yoshinori Matsuda

【Purpose】

To facilitate the smooth introduction of the CM in Japan by addressing issues of the CM together with industries, regulators and academia and by sharing our knowledge.

【Members】

- PMDA (assessors, GMP inspectors)
- National Institute of Health Science (researchers)
- Universities
- Industries (Daiichi-Sankyo, Eisai, Sumitomo Dainippon Pharma, Chugai, GSK, Janssen, MSD etc.)

Points to Consider Regarding Continuous Manufacturing (2017)

## Clarification for CM Implementation

## A draft Points-to-consider document.

We are focusing on 4 topics

- Control Strategy
- Batch Definition
- Process Validation
- Stability Testing

Note : This document assumes drug products of chemically synthesized drug.

# 今後の計画

## 連続生産研究会設立；趣意書

ときː12月13日（金）
ところː東京丸の内　オアゾ
　ラトガース大学 - 岐阜薬大ジョイントシンポジウム

2018～2019年度
ところː岐阜薬大
　趣意書に基づく活動と課題研究

1）連続生産装置を用いた製造技術の確立（基本技術の確立）
2）規制要件の詳細な検討とそれを満たす製造技術・管理戦略の確立（規制と製造技術の融合）
3）連続生産の推進を目指した国際会議の開催を通じた情報交換（国際調和の推進）