Research in Specialization Studies in Industrial Pharmacy benefits pharmaceutical industry

SUMMARY
Several research projects in Industrial Pharmacy Specialization Studies have been finalized to the benefit of pharmaceutical industry. B. Sc. in Pharmacy working in pharmaceutical industry have done literature studies and developmental projects related to the topics of their daily work. For M.Sc. in Pharmacy, the research projects have resulted in licentiate thesis (2 scientific publications). The topics of the latest published research projects are development and usage of GMP auditing tool, development of Key Performance Indicators for quality assurance, outsourcing of regulatory affairs as well as effects of moxonidine and atenolol on insulin sensitivity, postmenopausal symptoms and blood pressure in hypertensive postmenopausal women.

Key words industrial pharmacy, specialization studies, auditing, key performance indicators, outsourcing, regulatory affairs
INTRODUCTION
Specialization Studies in Industrial Pharmacy are a postgraduate program for Master of Science (M. Sc.) and Bachelor of Science (B. Sc.) in Pharmacy working in pharmaceutical industry in Finland or abroad. Currently, this program is international (42% of our students are from abroad) and the call is open yearly in January-April. Since 1992, when the first Specialization Studies in Industrial Pharmacy started, several research projects have been conducted in University of Helsinki to the benefit of the society. For industrially employed M.Sc., these projects have been licentiate theses with the topics related to the students’ daily work. These research projects have included either laboratory or qualitative research like surveys and interview studies. For B.Sc. the projects have been mostly literature studies on the topics related to their work descriptions or shorter development projects e.g. tools for daily work providing practical support for their working environments such as development of standard operation procedures, storage systems, databases, methods etc. The literature studies done by B.Sc. have been valuable for the pharmaceutical companies to give a deeper knowledge on the focus areas of interest.

The research projects included in Specialization Studies in Industrial Pharmacy have been previously related to a licentiate thesis (i.e. requirement of two parts of Specialization Studies with a student fee and due to the fact that it is challenging to conduct academic research, while working full time in pharmaceutical industry. However, after finalizing the Specialization Studies in Industrial Pharmacy, it is possible to continue to the doctoral studies. An example of such project is Ph.D. (Pharm.) Kirsi Rosenqvist’s dissertation project on the effect of systemically and locally administered clodronate on bone quality (Rosenqvist 2014).

To date, all together 57 B.Sc. and 9 Licentiate in Pharmacy have graduated from the Specialization Studies in Industrial Pharmacy from University of Helsinki. The last four licentiate theses, which have been finalised have had the following topics: 1) Anu Linna from Orion made her thesis on development and the use of Good Manufacturing Practice (GMP) audit preparation tool in pharmaceutical contract manufacturer audits in 2010; 2) Marianne Torkko from Orion investigated key performance indicators (KPIs) in quality management in 2014; 3) Satu Kujala from Medfiledes studied the effects of moxonidine and atenolol on insulin sensitivity, postmenopausal symptoms and blood pressure in hypertensive postmenopausal women in 2016; and 4) Anu Gummerus working at DRA Consulting graduated with the topic ‘Outsourcing Regulatory Affairs in Pharmaceutical Industry in 2017.’

GMP Auditing of Contract Manufacturers
In Anu Linna’s research project, the questionnaire tool for GMP auditing of contract manufacturers was developed (Linna et al. 2008, 2010). Firstly, the questionnaire was designed and validated with a Delphi method by getting feedback of the relevance of the questions asked from the GMP experts. In the second part, the objective was to evaluate the usefulness of the developed tool in audit preparation and during the actual GMP audit. Validity of the information given through the tool was examined by comparing the responses to the actual conditions observed during the contract manufacturer audits. Additionally, the contract manufacturers’ opinions on the tool were gathered and the auditors were interviewed. The developed tool was proven to be useful in audit preparation phase from both the auditor’s and the contract manufacturer’s point of views. Furthermore, usage of the developed tool can save time when performing the audit. The results show that using the tool can give significant support in audit preparation phase and during the actual audit. These types of tools are nowadays regularly used in GMP audits.

Quality Key Performance Indicators for Pharmaceutical Industry
Marianne Torkko studied Key Performance Indicators (KPIs) in quality management (Torkko et al. 2013, 2014). Firstly, she studied what type of quality KPIs companies use and how they utilize the results of these KPIs in food and pharmaceutical industry. Additionally, the contract manufacturers’ opinions on the tool were gathered and the auditors were interviewed. The developed tool was proven to be useful in audit preparation phase from both the auditor’s and the contract manufacturer’s point of views. Furthermore, usage of the developed tool can save time when performing the audit. The results show that using the tool can give significant support in audit preparation phase and during the actual audit. These types of tools are nowadays regularly used in GMP audits.

Medical Treatment of Hypertensive Postmenopausal Symptoms
Satu Kujala studied two articles on her previous clinical studies at Alqol on the effect of an imidazoline-1-receptor agonist (moxonidine) and a beta-blocker (atenolol) on insulin sensitivity, postmenopausal symptoms and blood pressure in hypertensive postmenopausal women (Kaja ym 2007, Kujala ym 2014). The aim was to compare the short-term effects of these two sympatholytic antihypertensive drug treatments, the peripherally acting β-blocking agent and the centrally acting imidazoline-1-receptor agonist in postmenopausal women with diastolic hypertension and obesity. Insulin sensitivity was measured by two different methods in subjects stratified by fasting plasma insulin level at baseline and by blood pressure response at the end of follow-up. In addition, the postmenopausal symptoms and their relationship to antihypertensive effect and the interaction between the effect on insulin sensitivity and menopausal symptoms were studied.

The severity of hot flushes and palpitations were reduced significantly in both treatment groups. In the atenolol treated group, one in every three patients (33%) reported relief from insomnia, and lightly fewer patients (27%) stated that their so-called General Impression of Sleepiness (GIS) score was also significantly improved. The levels of irritability declined in both pressure responders in the atenolol group. There was no correlation between the improvement in insulin sensitivity and the relief of postmenopausal symptoms.

This thesis is an example project from the early years of Specialization Studies when the industrial pharmacy research projects were started in collaboration with other disciplines, like pharmacology as in this case.

Outsourcing of Regulatory Affairs
Anu Gummerus investigated what kind of regulatory affairs tasks are outsourced, what are the reasons for outsourcing as well as the values and disadvantages of outsourcing these tasks in the pharmaceutical in...
distry in the EU countries (Gummerus ym. 2016a, 2016b). The aim was also to study how many con-
tact research organizations (CROs) pharmaceutical companies outsource their regulatory affairs tasks and
duration of outsourcing partnerships between these companies.

According to the responses, 65% of the pharma-
ceutical companies have outsourced tasks related to
research and development over the last three to five
years. Over 44% of the respondents informed that they
have outsourced to one or two CROs only. One
quarter of the respondents have outsourced to three
to five CROs. The principal reason for outsourcing
regulatory affairs tasks to a CRO was the excessively
heavy workload in the company’s regulatory affairs.
Also, outsourcing should be cost-effective.

The fact that a CRO has experience and knowl-
edge was seen as a very important requirement when
choosing the CRO partner. Personal, individual con-
tacts were mentioned in many of the open-ended re-
sponses as an essential criterion in the selection of
the CRO. Most (91%) of the respondents in the phar-
maceutical industry strongly agree and agree on the
fact that they outsource the regulatory affairs tasks
because they want to obtain greater flexibility. The
companies evaluated that outsourcing to CROs is ex-
pensive (strongly agree or agree 74%). CROs have to
maintain the quality level high and obtain flexibility
towards the outsourcing companies.

When a company is considering outsourcing reg-
ulatory tasks, planning has to be done well in ad-
vance. The main topics to be discussed between the
outsourcing company and CRO before the outsourc-
ing process are estimated costs of the outsourcing,
outsourceing strategy, information flow and audit
trails. Quality provided by CRO plays a significant
role when the companies select their partner. The
CRO has to assure uniform quality in their personnel
knowledge and skills despite of personnel changes.
Practically, all product development steps can be out-
sourced by local or multinational CROs. These Anu
Gummerus’ publications are also frequently read by
international pharmaceutical industry (1700 reads
since 2015 in ResearchGate).

On-going Research in Specialization
Studies in Industrial Pharmacy
Since the students come from different types of phar-
maceutical companies (i.e. small or big; originator or
generic; CROs, wholesale or manufacturing) and ad-
ditionally from the different functions within these
companies, it is difficult to find larger themes for the
research topics. The research projects are tailor-made
for the students relating to their daily work or inter-
est and the suitable supervisors and support will be
organized for their specific needs.

Currently, there are altogether 30 research projects
on going for M.Sc. and 20 studies for B.Sc. in indus-
trial pharmacy. The great variety of topics for M.Sc.
can be seen: nutraceuticals, customer research ser-
dices for pharmaceutical industry, quality manage-
ment system for regulatory affairs, medication faults
related to dosing of medication in intensive care unit
of neonates, authority practices in biosimilars, effect
of lubricant, relative humidity and amount of sorbi-
tol on compression of xylitol/sorbitol mixtures, work
against drug counterfeiting and degradation of biop-
harmaeuticals with contact of reducing disacchar-
idases, serialisation and pharmacovigilance.

The projects, which are related to a company’s
know-how, have to get a publication permission from
the companies. Therefore, co-supervision of the sci-
entific work has to be organized within the compa-
nies, too. This is sometimes challenging in smaller
companies having no PhD as staff members. Further,
the literature studies and research projects of B.Sc.
have not been previously published, since students
have not applied for publication permission from the
companies. This will be developed in future, since the
knowledge obtained in these projects might be use-
ful for larger audience. There are plans to start pub-
lishing these projects in the public university data-
bases, which then requires publication permission
from the companies. For literature studies this is not
a problem, but for developmental projects this might
be a challenge.

To conclude, all these research projects will give
additional and deeper understanding on the current
issues of the working environment for the students or
tools to improve their daily work. These research
projects have shown general interest not only in Fin-
land but also internationally. Since 2008, industrial
pharmacy has been a stand-alone discipline featuring
research, development, manufacturing, marketing and
distribution of pharmaceutical products as well as
their related quality assurance. To our knowledge,
this full academic discipline of industrial pharmacy
with this scope is unique in the world.

TIIVISTELMÄ
Teollisuusfarmasan erikoistumiskoulutuksen yhteydessä tehty tutkimus
hyödyttää lääketeollisuutta

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Conflict of interest:
Anne Juppo: Consultation in IPR matters for
Orion Pharma, Finland 2017; Member of Scientific
Committee of Orexo, Sweden 2017; EU project
secondment, Zentiva, Czech Republic, 1 month
in 2018
Mia Sivén: EU project secondment, APC, Ireland
1 month in 2018-2019; Invited speaker, Continuing
Professional Development (CPD) event, Tamro,
Finland 2018

Avainsanat:
teollisuusfarmasia, erikoistumiskoulutus, auditointi,
alusta, myyntilupahtava ulkoistaminen

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REFERENCES


