Institution: University of Nottingham

Unit of Assessment: UOA3 (Pharmacy)

a. Context

Since 2008 research from across the School, aligned along our 'Bench-to-Society' strategy, has had demonstrable impact in a range of diverse areas including Health and Welfare, Society, Culture and Creativity, Economy, Commerce, Public Policy, and International Development. Major beneficiaries are related to Healthcare (patients, medical charities, drug companies, SMEs), Pharmacy Practice (government bodies, pharmacists, pharmacy users) and Public Engagement (teachers, pupils, general public). In partnership with our collaborators we ensure that our impact is experienced locally, nationally and globally, as relevant. The School has a long history of translating excellent research into impact and each of our 5 Research Divisions plays an active role in building on this legacy. Examples of our impact are highlighted below.

Medicinal Chemistry and Structural Biology (MCSB) The Division has a long track record of drug discovery and development. Strong links with Cancer Research UK have enabled product development and clinical studies of our most advanced molecular candidates and global licence agreements with industry (e.g. Pharminox, Changzhou Le Sun Pharmaceuticals) to progress improved treatments to market (Case Study 2). The spin-out company CellAura provides drug discovery products to the pharmaceutical industry as safe, cost effective, high-throughput, non-radiolabelled tools for ligand-binding studies (Case Study 3).

Molecular and Cellular Science (MCS) Advances in molecular biology and parasitology have enabled hookworm therapy for allergy and autoimmune diseases to undergo clinical trials in the UK and Australia (Current UK Phase II trial funded by the Multiple Sclerosis Society). A recent patent application covering markers of pseudomonas infection is already receiving commercial interest.

Drug Delivery and Tissue Engineering (DDTE) Two spin-out companies, RegenTec Ltd and Critical Pharmaceuticals Ltd, are pioneering approaches to cell therapy and new formulation technology, respectively. An inhaled formulation of Human Growth Hormone developed using Critical's technology successfully completed Phase I trials in 2013. As co-director of the EPSRC Centre for Innovative Manufacturing in Regenerative Medicine (£5.8M, EP/H028277/1), we are helping to translate research into regenerative treatments for clinical use, with partners including Pfizer, Neusentis and Nottingham University Hospitals NHS Trust (US/61/842507). Patented polymers designed for gene delivery (WO2008038038) have been modified for use in water pollution studies (WO2012020230; assigned to Envirogene and now DNA Tracer Technologies).

Laboratory of Biophysics and Surface Analysis (LBSA) Advanced analytical methodologies have been translated into the spin-out Molecular Profiles Ltd (MP; Case Study 1), and provide the pharmaceutical industry with critical formulation insights bringing drugs to the market in cost effective ways and enabling optimisation of in-house strategies (Case Study 4). A new class of polymers resistant to bacterial attachment has been identified. Wellcome Trust funding and industry collaborations are translating the resultant patent family (WO2012150467) to products. The University spin-out Eminate Ltd, co-founded by the LBSA, translates IP through licencing to the market. Substantial exclusive global licence deals, including royalties, have been agreed with Tate&Lyle: in 2012 for a salt reduction product, SODA-LO Salt Microspheres™ (WO2009133409, now launched globally; Best University Product PraxisUnico 2013 'Impact Achieved' category); and in 2013 for a reduced-sodium Sodium Bicarbonate product (WO2013124652).

Social Research in Medicines and Health (SRMH) Studies have informed UK Government health policy leading to effective provision of public health services via pharmacies (Case Study 5) and updates to the Yellow Card Scheme. Cost reduction and potential life saving measures within the NHS have been developed or evaluated: the PINCER trial (pharmacist led intervention for medication errors) and the New Medicines Service. Leadership roles have managed evaluation of services for patient benefit (NIHR Research for Patient Benefit East Midlands Committee) and developments in worldwide pharmacy education, particularly in Africa (FIP WHO UNESCO Global Pharmacy Education Initiative). Our health economists evaluate cost effective treatment options for use within the NHS through representation on the NICE Technology Appraisals Committee.

The School also takes pride in its outreach and public engagement activities where our research is helping to promote the importance of science in education (via outreach to local schools) and broadening public understanding of controversial science topics such as nanotechnology, stem cells and artificial life (via community open days, exhibitions (e.g. Royal Society) and YouTube).

b. Approach to impact

Strategic oversight of Knowledge Transfer (KT) The School has a pro-active approach to impact and set up the Knowledge Transfer Committee (KTC; reports to the School Management Committee) in 2009 to manage impact related activity. The KTC is chaired by a senior member of the School, with experience in innovation and who sits on the University Innovation Board. Membership also includes the School-funded Business Development Officer (BDO), representatives from each Research Division, members of the University Technology Transfer team and an External Industrial Advisor. The Committee meets quarterly, its remit includes: identification and promotion of KT funding calls; assisting our Grant Academy on KT applications; overseeing the School's Intellectual Property (IP) strategy, including early identification of IP opportunities via the BDO; review of research portfolios to maximise impact potential; and organising impact related events and staff training. A key aspect of our approach to impact is to obtain regular external review. Each of our Research Divisions is reviewed on a rolling basis for quality of research outputs, impact and strategic planning.

Commercialisation of IP The School's IP is protected via invention disclosures, mostly in the form of patent applications. Regular consultation with staff allows potential disclosures to be considered by the KTC and refined by the academic team and BDO prior to consideration by the University's Knowledge Transfer and Innovation Boards. The School's active IP portfolio includes 33 patent families of which to date 17 are granted patents. We also have 3 examples of non-patented IP which continue to generate royalties. Since 2008 there have been 32 new patent family filings (of which 16 are progressing toward grant) and 14 licensing and assignment deals with commercialisation partners. The School has a long track record of commercialising research through spin-out companies, dating back to the early 1990s. Several of our early spin-outs have exited via buyouts (e.g. DanBioSyst, Pharmaceutical Profiles, Spirogen (total in excess of £30M)). Our current spin-out portfolio (MP, Onc-Immune, CellAura, RegenTec, Critical Pharmaceuticals, Eminate) are helping to grow the economy, currently employing 124 skilled staff and attracting grant investment such as: UK Regional Growth Fund (£1.6M MP), Wellcome Trust (£1.5M Critical, £0.9M RegenTec) and Technology Strategy Board (£1.2M Critical, £1.4M RegenTec). Following negotiations during 2013, MP was acquired by Columbia Lab Inc. for $25M in September 2013.

Maximising KT funding opportunities We recognise the need to mature technologies prior to commercialisation and have been successful in seeking investment from a variety of sources to progress pipeline technologies in their route to impact. Smaller awards are used to fund initial feasibility studies, before staff apply for larger, proof-of-concept or development funding. Since 2008, we have been awarded over £9M to support technology translation, including major awards from the Wellcome Trust (>£2M, 2008), EPSRC (£897k, 2009), and the National Measurement Office (£4.3M, 2013 in partnership with the National Physical Laboratory (NPL)) to progress technologies including new selective "beta blockers", bacteria resistant polymers for use in medical devices such as catheters and stents, regenerative medicine therapies, and new methods for studying drug transport in cells. School funds are strategically used to support translational research, e.g. contributing to patent costs (ca. £22.5k since 2008) and to secure and service an MHRA licence for clinical trials manufacture in 2011 (£8k). This facility provides cGMP *Necator americanus* for a Phase II clinical trial of hookworm immunotherapy to treat Multiple Sclerosis. Members of the School are active in several of the University's Research and Knowledge Transfer Priority Groups, set up in 2010 as a mechanism to deliver world-class research and generate impact, including those in Drug Discovery, Biomedical Imaging and Advanced Manufacturing.

Establishing strong relationships with industry Our staff, supported by our business engagement team, have forged strong links to the pharmaceutical and related industries resulting in 73 active collaborative projects worth over £4.5M with 47 companies, over the REF period. Our two EPSRC Centres for Doctoral Training (CDT), in Targeted Therapeutics and Regenerative Medicine, both have strong industrial links. The Targeted Therapeutics CDT is 50% funded by

industry (AstraZeneca, Pfizer, GSK, Quotient Clinical, and Boots Pharmaceuticals) and uses the EPSRC 'Sandpit' model to develop industrially relevant PhD projects. We regularly engage with the University's Business Engagement and Innovation Services (BEIS) who have helped to set up collaborations, including EPSRC funded KT Secondments (KTS) with Pfizer and IHolland. The IHolland KTS subsequently led to a TSB funded 2 year KT Partnership (2012), with a new product to reduce sticking during tableting under development. Staff engage with industry through bi- and multi-lateral events, including: 'Innovation Days' at BioCity Nottingham with SMEs; training/career events with pharma; and one-on-one 'showcase days' with targeted companies. For example, we were selected by Nitto Denko Corp (Japan) following their global search for partners to allow them to enter the pharmaceutical market. The resulting drug delivery technologies are now under patent protection (WO2010001932; WO2011040597) and are being further developed by Nitto Denko.

Enabling staff engagement with KT Staff are supported in undertaking external roles (eg. committees, consultancy, board or advisory group membership) via a workload planning model which takes account of teaching, administration, research, and external activities (allowing up to 20% of time to be spent on external engagement). Our links to UK Government departments and other national and international leadership roles (described earlier) have been supported in this way, as well as on-going relationships with our spin-outs. External activities are promoted via annual performance review and career progression management due to the extensive benefits for all parties. Our School sabbatical programme (54 sabbaticals since 2008) has also led to impact related activity, for example a sabbatical to MIT in 2004 initiated the research which resulted in a patent application on bacteria resistant polymers being filed in 2012 (WO2012150467).

The School provides impact training to all research staff. Our KTC works with the University's BEIS team to offer training sessions on topics such as IP protection and mentors staff on KT processes. Our PDRAs and PhD students undertake the University's Graduate School courses on impact and we are especially proud of our training in entrepreneurship in which researchers develop business plans and compete for virtual investment. Following impact training, one of our CDT students was awarded an EPSRC Doctoral Prize to translate his PhD research into new cost effective pharmaceutical formulations. An idea for a reagent management system, developed through the School's "Environmental Impact" business competition, is to be piloted within the University. We led the RCUK India Science Bridge BioPharm2020 initiative running business incubation competitions in 2010 and 2012. 20 teams were mentored by industrial experts with two new companies being set up: Platelet Solutions Ltd in the UK, and Crystalin Research PVT in India.

Public engagement and outreach The School uses University services to help in outreach and public engagement; we also have staff who oversee outreach. The University's Communications and Marketing Team have helped to organise and promote School events such as the NanoWhat exhibition which toured the East Midlands in 2008 attracting 23,000 people including yr 7-8 students from 40 schools, and the "Biology Builders" who showcased 3D Stem Cell Printing at the University's 2013 MayFest Community Open Day, and exhibited at the 2013 Royal Society Summer Exhibition (School support £10k), which was attended by 12,505 people including 2,618 school students. Feedback from the event was positive and indicated respondents had gained new knowledge. The School participates in two annual Summer Schools where our research is showcased, organised by the University Widening Participation team, which encourage students from deprived backgrounds to consider studying science at university (of 167 participants on the Pharmacy related tracks since 2008, 29 have enrolled on STEM courses at Nottingham).

c. Strategy and plans

Our current approach to impact, linked to the University's Knowledge Engagement Framework, has been highly productive and is reviewed on a rolling basis to ensure a strategy fit for purpose, with short, medium and longer term targets and priorities.

Short term We are investing in new posts in partnership with end users to grow research with new opportunities for impact. An Interface and Surface Analysis Centre has been set up via a University Strategic Development Fund in partnership with NPL (£410k seed funding, 2012-17) alongside the National Centre of Excellence in Mass Spectrometry Imaging established in 2013. This has created two academic posts and a dedicated Business Manager to drive industrial and clinical uptake of

technologies developed. In clinical pharmacy, we have made a joint appointment with Nottingham University Hospitals NHS Trust (2012) to study the impact of analgesic medication on clinical outcomes. To further increase patient-focused translational research we are offering 5 year "Research Practitioner" programmes from Sept 2013, creating opportunities for pharmacists to complete PhDs whilst maintaining their professional roles. This is in response to Medical Education England's 2012 report "Modernising Pharmacy Careers Programme" which showed that few early career pharmacists undertake high quality research. Such research offers efficient routes to impacts on patient care by providing evidence to support practice and policy changes.

Medium term We will continue to engage new members of staff and research students in our impact activities so as to secure KT funding and/or achieve impact. The School holds the Directorship of the University's EPSRC funded Impact Acceleration Account (EP/K503800/1, £2.6M) and will use the objectives of this Account to further develop our KT culture. We will appoint an "Impact Champion" to work closely with the BDO and KTC to mentor staff, particularly early stage researchers, and promote a greater engagement with impact activities and training.

The School is investing in strategic partnerships to address national and international translation agendas. For example, we are investing £20k to develop new collaborations in Europe and are a key part of a new consortium, including top UK Pharma, aiming to found a new TSB funded national centre for formulation. As the Pharmaceutical Industry increasingly outsources specialist research, our coordinated and targeted approach is designed to ensure we capitalise on this. Additional strategies to increase industrial collaboration include the promotion of specialist equipment in the School (eg. 3D Nano SIMS with NPL and GSK) and exploiting our research alumni network to grow external engagement. We are also working towards deeper industrial engagement through renewal of both of our EPSRC CDTs, which include wider industrial support. The School will also maintain its policy of matching funding for all joint industrial PhD studentships.

Long term The School is establishing a new Division for Innovation in Pharmacy Education through which we aim to broaden our impact on the education of professional Pharmacists and Pharmacy technicians. We have extensive global industry links, especially in the EU and US, and foresee increased impact through greater exploitation of the research base in our School of Pharmacy in Malaysia and our China campuses. This is evidenced by recent joint EU funding with our Malaysia colleagues (FP7 Biodesign Project €843k) and our plans to establish an industry led doctoral training centre at our Shanghai-Nottingham Advanced Academy.

d. Relationship to case studies

The School is submitting the following Case Studies alongside this template:

1. Commercialisation of Advanced Pharmaceutical Formulation, Analysis and Manufacture via Molecular Profiles Ltd
2. Commercialising Benzothiazole Compounds for Use in Diagnosis and Development of Treatments for Alzheimer's Disease
3. Commercialisation of Fluorescent Ligand Technologies for Advancing Receptor Pharmacology and Drug Screening
4. Supporting the Regulatory Approval of Poorly Soluble Drugs for HIV and Hepatitis C
5. Delivering Public Health Services Through Community Pharmacy

Following successful spin out developments (e.g. Case Studies 1 & 3) and patent licensing (e.g. Case Study 2) in the 1990s and early 2000s, the School appointed a dedicated Business Development Officer (Dr Gilbert) in 2005 to oversee the increasing amount of impact activity. We formed the KTC in 2009 to set up and manage an effective impact strategy following expansion of the School's research base and resulting uplift in impact activity. Our strong ties to the Pharmaceutical industry have resulted in major benefits to our partners (e.g. Case Study 4). We aim to capitalise on this reputation as the Industry refocuses its activities. This has led to our wider global perspective and more targeted approach to industry collaboration. Facilitating external activities has led to wider recognition of our staff and their research, resulting in commissioned studies used to inform government policies (e.g. Case Study 5). We will therefore continue to encourage external activity, through workload planning, as part of our impact strategy.