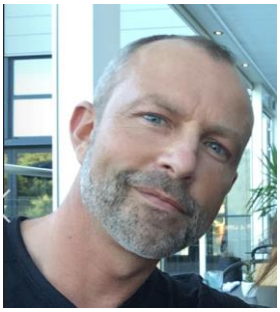

Dr Craig Steven HARRIS PhD FRSC
51 years old, married with
2 children (24, 21 yrs old)
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Driving & motorboat licence

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CMC Drug and Dermal Filler Development | People Leadership and Development | Continuous Improvement | Innovation | Problem-solving

A NCE (new chemical entity) drug development leader and scientific advisor with more than 25 years' experience in small molecule drug discovery & development working in big pharma alongside 5 years' experience in HA-based dermal filler R&D and trouble-shooting marketed products (eg., OOS, OOT) resulting in several success stories, avoiding market recalls and costly re-processing through sound science. I am not afraid to innovate within the scope of the project or task in hand and have a strong track record of tangible creativity (>100 scientific communications) spanning from enabling access to hard-to-make design space in a drug discovery setting all the way to significantly improving established API routes permitting net commercial gain.

PROFESSIONAL EXPERIENCE

June 2023- **Founder and CEO of CMC Innov Consulting SAS** (France)
Consultancy company specialising in chemistry, manufacturing, and controls' activities with a profound expertise in organic synthesis, chemical development and troubleshooting.

Dec 2020 **Head of Small Molecule Development & Scientific Advisor (Senior Principal Scientist) – Global R&D – CMC – GALDERMA SA** (Switzerland) - Dermatology
Promotion. Accountable for all small molecule drug substance and drug product development with particular expertise in topical drug development. Other responsibilities include CMC leadership of early development programs (topical & aesthetic), providing technical advice for dossier submissions, to other departments (*eg.,* Formulation, Quality, Regulatory Affairs, Industrial Development, Procurement, IP) and supporting legacy product small molecule drug substance activities.
Main achievements
- CMC Lead for 3 small molecule kinase projects (2 topical and 1 oral) and 1 aesthetic project with all projects meeting their CMC milestones within the fixed timeframe under the umbrella of COVID-19.
- Technical lead for the global nitrosamine strategy. Construction of risk assessment templates, risk evaluation for all drug substances and drug products across all sites.
- Stabilization of several DS processes after numerous OOS / OOT through cross-site and highly collaborative scientific approaches with significant cost-savings for Operations.
- Technical support for small molecule dossier submissions, questions from competent authorities, 2nd sourcing projects, due-diligence, patents and for Quality Departments to make decisions namely through troubleshooting supported by position papers and toxicological assessments.
- 15 Patents, external publications and presentations.

Feb 2019 **Head of Chemical Development & Scientific Advisor (Senior Principal Scientist) – Prescription GBU - CMC – GALDERMA SA** (Switzerland) - Dermatology
Promoted to Scientific Advisor providing support for all API synthesis activities from lead generation up to cGMP manufacture of drug substance including supporting legacy product drug substance activities.

Sep 2018 **Senior Expert Scientist (Principal Scientist) for API Synthesis – Prescription GBU - NESTLÉ SKIN HEALTH** (Switzerland) - Dermatology
Chosen to lead the entire synthesis for the group adopting a virtual R&D or 100% outsourced organisation model.

Nov 2014 **Head of Research Synthesis / Senior Expert Scientist (Principal Scientist) – NESTLÉ SKIN HEALTH** (France) - Dermatology, Aesthetic & Corrective Fields
Responsible for driving a large team of up to 15 chemists internally and for all external (CRO) small molecule and hydrogel synthesis activities for Galderma-Nestlé Skin Health Research on the Sophia site.

Main achievements

- Delivered >60% in terms of principal KPIs (key performance indicators) over 3 years and drove the synthesis of 8 development candidates for rosacea, acne (Caspase I, RORyt), skin cancer (HDAc) and psoriasis (TACEBu, RORBic)
- Active management of CRO synthesis support (selection, strategy, problem-solving, negotiation) to Rx and A&C projects on a FFS and FTE basis
- Principal contributor to the recruitment and installation of a new dermal filler research team on the Sophia Antipolis site with several innovative projects in the preclinical and clinical phase including the clinical candidate Novolink
- Chair of A&C cross-site innovation group with focus on BDDE-free hydrogels (*eg.,* Novolink) and integration of skin-essential minerals in gel formulations. New dermal platform discovered and to be marketed from Q4 2025.
- Increase of >400% in scientific communications from the group including initiation of an annual chemistry symposium with the University of Nice
- 32 Publications, patents and external presentations have been released during this period

Apr 2013 **Head of Research Synthesis – GALDERMA R&D** (France)- Dermatology
Responsible for driving a large team of up to 12 chemists internally and for all external small molecule medicinal chemistry research.

Nov 2012 - Mar 2013 **Principal Scientist – Chemistry – ADOCIA** (France) - Biotechnology
Senior scientist implicated in project construction for an innovative biopharmaceutical company. Developed particular expertise in the field of polysaccharide modification for protein-delivery vehicles.

2000-2012 (12 years) **Associate Principal Scientist (Chemistry Team Manager) - ASTRAZENECA** (France) **–** Oncology iMed
Responsible for driving synthesis teams, including external CRO activity, to support discovery medicinal chemistry projects in the oncology research area.

Main achievements

- Twelve years' experience in synthesis management, internal and external through CROs, to support delivery of 15 oncology projects including three developments compounds (AZD1845, AZD4679 and AZD8835)
- Nominated to lead the cross-site *Global Synthesis Network* from 2010 by the AZ Global Chemistry Network (therapeutic area chemistry directors)
- Key Process Owner for local and global continuous improvement projects
- Fully accredited Innovation Coach by CCMR Consultants Ltd
- 42 External publications including presentations and patents were released surrounding problem-solving within the scope of the projects
- 8 Global AstraZeneca Awards for achievement in drug discovery synthesis

1999-2000 (18 months) **Senior Research Chemist - ASTRAZENECA** (U.K.) **–** Oncology iMed (secondment)
Route conception and execution to deliver novel final compounds namely for kinase targets. SHE laboratory lead and Process Research & Development key contact.

Main achievement

- During this period, our team accessed several unexplored targets in two projects by providing novel chemical routes resulting in several publications.

1997-1999 (18 months) **Senior Process Research Chemist - ASTRAZENECA** (U.K.) - Pharmaceutical Development
Develop robust and commercially viable processes for plant-scale operations. Developed a strong expertise in industrial-scale solid supported peptide synthesis.

Main achievements

- Development of a solid-phase peptide process to deliver 4 kg of a decapeptide (WO2000075171)

Preparation of the key lactam fragment (WO9955669), "Boc-Lactam-OH", reducing epimerisation (8-12% to 0.05%), which was the key driver to switch to a solution-phase route (WO2002008247) resulting in significant cost-savings for campaign 5 (>20 kg).

EDUCATION

1993-1997 **Ph.D. in Organic Chemistry** under the supervision of Professor David Leigh (UMIST now Manchester University, U.K., ranked 29th in QS World Rankings 2018, link & 7th in the U.K. link).

1990-1993 **B.Sc. (First Class Honours)** and first-placed graduate specialising in Medicinal Chemistry (UMIST now Manchester University, U.K., ranked 29th in QS World Rankings 2018, link & 7th in the U.K. link).

PATENTS, PUBLICATIONS, PRESENTATIONS & PRIZES (>100)

Author / co-author / inventor / co-inventor of 53 papers (>600 citations, HI Index 14, RI Score >300 (link)), 34 patents and 18 external presentations recognised with several awards.

PATENTS

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- Arnould, Jean-Claude; Harris, Craig Steven; Boyle, Francis Thomas; Gibson, Keith Hopkinson. *Preparation of 3,4-disubstituted maleimides derivatives as vascular damaging agents.* WO2005102997 (link).
- Arnould, Jean-Claude; Delouvrie, Benedicte; Harris, Craig Steven**.** *Preparation of N-[heteroarylcarbonyl]-3-thienyl-L-alanine derivatives as α5β1 antagonists.* US2008255183 (link).
- Barlaam, Bernard Christophe; Bower, Justin Fairfield; Delouvrié, Bénédicte; Fairley, Gary; Harris, Craig Steven; Lambert, Christine; Ouvry, Gilles; Winter, Jon James Gordon. *Pyridine and pyrazine derivatives as Axl and/or c-Met receptor enzyme inhibitors and their preparation, pharmaceutical compositions and use in the treatment of tumors.* WO200905373 (link).
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- Barlaam, B. C.; Delouvrie, B.; Ouvry, G.; Lambert-Van der Brempt, C. M. P.; Harris, C. S.; Berry, D.; Tomkinson, G. P.; Reid, G. P. U.S. *Preparation of novel aminopyrazine derivatives as antitumor agents*. US20140206700 (link).
- Harris, Craig S.; Olsson, Johan. *Method for deacetylation of biopolymers.* WO2017114861 (link).
- Harris, Craig S.; Olsson, Johan. *Carbohydrate crosslinker.* WO2017114867 (link).
- Harris, Craig S.; Olsson, Johan. *Method for cleaving amide bonds.* WO2017114859 (link).
- Harris, Craig S.; Olsson, Johan. *Hydrolysis of ester bonds in amide crosslinked glycosaminoglycans.* WO2017114865 (link).
- Harris, Craig S.; Olsson, Johan. *Method for preparing acylated crosslinked glycosaminoglycans.* WO2017114864 (link) .
- Ouvry, Gilles; Bhurruth-Alcor, Yushma; Harris, Craig S.; Deprez, Benoit; Bourotte, Maryline. *Preparation of benzenesulfonamides and use thereof in medicine and cosmetics*. EP3199534 (link).
- Harris, Craig S.; Olsson, Johan. *Method for cleaving amide bonds using hydroxylamine salt while preserving protecting groups and/or chiral centers.* WO2017207564 (link).
- Harris, Craig S.; Jing, Jing. Hyaluronic acid gel with a divalent zinc cation. WO2018055002 (link).
- Harris, Craig S.; Jing, Jing L.; Edsman, K., Karlsson, A. Glycosaminoglycan gel with bis-tris buffer for cosmetic and medical uses. WO2019002371 (link).
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- Harris, Craig S.; Ouvry, Gilles; Bouix-Peter, Claire *et al*. Novel JAK inhibitor compounds, method for synthesizing same and use thereof. WO2022053931 (link).
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- Harris, Craig S.; Ouvry, Gilles; Bouix-Peter, Claire *et al*. Novel JAK inhibitor compounds, method for synthesizing same and use thereof. WO2022054005 (link).
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- Harris, Craig S.; Vial, E. Zanelli, U. Preparation of pyrazolopyrimidines as novel mTOR inhibitors useful in treatment of diseases, WO2023031738 (link).
- Harris, Craig S.; Bouix-Peter, Claire; Crosagnini, Stefano; Campos, Sebastien; Talbot, Eric; McClean, John. Protein kinase c theta inhibitors, WO2023119098 (link)
- Harris, Craig S.; Tomas, Loic. Salt-screening of CD14547, filed Q1 2022.
- Harris, Craig S. Optimized large-scale synthesis of CD16736, filed.

PUBLICATIONS (* denotes principal authorship)

- Harris, Craig S.;* Kettle, Jason G.; Williams, Emma J. *Facile synthesis of 7-amino anilinoquinazolines via direct amination of the quinazoline core*. *Tetrahedron Lett.* **2005**, *46*, 7381-7384 (link).
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EXTERNAL PRESENTATIONS (visible *via* Researchgate (link))

- *Total synthesis of Atrasentan*. Invited talk given during a regional symposium at Reims University, **2002** (link).
- *Selective alkylation of a 6,7-dihydroxyquinazoline*. Invited talk given during a regional symposium at Reims University, France **2005** (link).
- *Systematic variation of a key quinazoline core*. Poster presentation given at the 22nd *ECHC Symposium* in Bari, Italy, **2006** (link).
- *Synthesis of highly substituted thienopyrroles and pyrroles as GnRH antagonists*. Poster presentation given at the *8th Tetrahedron Symposium* in Berlin, Germany, **2007** (link).
- *Synthesis of highly substituted thienopyrroles and pyrroles as GnRH antagonists*. Invited talk given at the *20th French-Japanese Symposium on Medicinal and Fine Chemistry* in Bordeaux, France, **2008** (link).
- *Novel synthesis of α-alkoxythiophene amino acids*. Presentation given during a regional symposium at Reims University, **2010** (link) and given at the 24th ECHC conference, Vienna, Austria, **2010** (link).
- *Three-point variation of a key quinazoline core*. Invited talk given at FloHet12, Gainesville, Florida, U.S., **2011** (link).
- *Synthesis of highly substituted thienopyrroles and pyrroles as GnRH antagonists*. Invited talk given at the 40th Birthday of the French Chemical Society, Reims, France, **2011** (link).
- *Diversity orientated synthesis of novel kinase inhibitors*. Invited talk given at the Ecole Polytechnique, Paris, France **2011** (link).
- *An expedient synthesis of novel, non-peptidic RGD integrin antagonists targeting α5β1*. Invited talk given at the 2nd Winter Process Chemistry Conference, Manchester, U.K. **2014** (link).
- *Annual Galderma-Nice University Symposium,* **2015-2017**. Initiator and co-organiser of this popular event to share innovative chemistry between Nice University and Galderma used principally as a development opportunity for our synthetic chemist community.
- *Synthesis enabling design: Two independent case studies of library route design and optimization*. Invited talk given at the JMJC, Nice, France **2016** (link).
- *Synthesis of selective inhibitors of Capsase I*. Invited talk given at Peptides U.K., London, U.K. **2017** (link).
- *Design and synthesis of novel peptidomimetic Caspase I inhibitors as a novel topical treatment for acne*. Invited short talk given at the 2nd Swiss Industrial Chemistry Symposium, Basel, Switzerland, **2018** (link).
- *Lean delivery of a sulfoxime-based RORγ inverse agonist for topical administration*. Featured speaker & presentation given at BOS, Basel, Switzerland, **2019** (link).
- *Transitioning towards a fully outsourced model in CMC - Showcasing Highly Collaborative Outsourcing Partnerships*. Invited speaker & presentation to be given at BOS, Manchester, UK, **2022** (link).

PRIZES & AWARDS

- ***AZ Global Oncology Publications Prize Winner,* 2005.** Recognition for authorship and co-authorship of 2 individual print publications and 3 patents in the same year together with presentations at internal symposia.
- ***AZ Global Oncology Innovation Award for Synthesis,* 2008**. Recognition for the design and synthesis of a chiral un-stabilised C-2 thiophene ether amino acid derived integrin ligand and successful collaborative work with Professor Richard Jackson (Sheffield, U.K.) (link).
- ***AZ Global Oncology Publications Prize Winner,* 2009.** Recognition for authorship of 4 individual print publications, 1 successful collaboration with Professor Jackson (*J. Org. Chem.*, **2010**, *75*, 245 (link)) and 1 patent in the same year together with presentations at internal symposia.
- Elected Oncology ***Reims "Local Star"*** and voted ***"best chemist"*** by oncology directors and rewarded with the honour of attending the *Nobel Prize Ceremony for Chemistry,* **2010.**
- ***AZ Global Oncology Publications Prize Winner,* 2011.** Recognition for authorship of 4 individual print publications, 3 invited talks and the first synthesis book chapter from Discovery.
- ***AZ Global Senior Scientist of the Year (Chemistry),* 2011.** Recognition for the discovery and application of a new aromatic primary amine protecting group with major advantages over existing protecting groups, having 5 papers accepted and having delivered 3 invited talks.
- ***AZ Global Quarterly Prize for Innovation,* 2012**. Recognition for having successfully directed the synthesis of 3 individual series in parallel to answer the shortest Lead Optimisation Identification Phase in AZ History. All 3 synthetic routes, with very little inter-route convergence, were sufficiently optimised for the immediate manufacture of large quantities of the APIs for comparative pre-toxicology evaluation. These routes were optimised in parallel with ongoing

final SAR probing. This huge team effort was rewarded with the successful nomination of the selected candidate AZD8835 (prepared on a scale of 5 kg over 15 steps, 29% overall yield) in September **2012**.

- Winner of ***AZ Abstract Prize*** (August **2008**, December **2008**, June **2011**, August **2012**).
- Selected by R&D Directors to propose an entry for the ***Nestlé Innovation Award*** **2018** concerning the pH neutral cleavage of amide bonds under aqueous conditions (WO2017114861, WO2017114859, *Eur. J. Org. Chem.* **2018**, *23*, 2995-3000 (link)).
- Awarded status of ***Fellow of the Royal Society of Chemistry*** (FRSC) namely for organic synthesis contributions to drug discovery, March **2018**.
- Often present in the monthly communications from the VP GBU Rx for **High Impact Contributions** during **2018-2020**
- Many internal Galderma ***"Galvanize"*** **awards** notably for innovative problem-solving for our development programs and for supporting legacy product trouble-shooting activities during **2021-2022**.

REFERENCES

Available on request or see LinkedIn recommendations (link) and testimonials on www.cmcinnov.com