

Candidate: Regional VP-Elect, Europe (2023-2025)



Qasim Rafiq, MEng, PhD

Associate Professor
University College London
United Kingdom

Summary of academic and professional background:

I am a multidisciplinary engineer working at the life science, engineering and commercial interfaces with a research focus on the bioprocessing, automation and biomanufacture of advanced therapies. I have a specific research and commercial interest in addressing the large-scale manufacturing challenges and enhancing process and product understanding to enable successful translation from laboratory to clinic.

I currently lead a research portfolio of >£5M as Principal Investigator, including a £1.8m EPSRC Early Career Fellowship (2022-2025) and >£20M as Co-Investigator. I lead the Cell and Gene Therapy Bioprocess Engineering group at UCL which includes 4 post-doctoral researchers and 11 PhD students. I have collaborated with >25 industrial and clinical partners and have an extensive track record of clinical and commercial delivery. Projects focus on addressing both upstream and downstream process development challenges for the production of autologous and allogeneic ATMPs for a range of clinical applications. Product applications include stem/stromal cells (mesenchymal, haematopoietic and pluripotent), extracellular vesicles and gene-modified immune cells.

I have also taken an active role in developing teaching and training activities, launching a new MSc programme at UCL in “Manufacture and Commercialisation of Stem Cell and Gene Therapies” in 2020, and actively involved in national and international training initiatives to deliver the scientific, technology and business leaders that will drive the industry forward.

Prior to UCL, I was an Assistant Professor at Aston University where I established the Bioprocess Engineering Group and led a research portfolio of >£1.5M. I completed my PhD at Loughborough University investigating the scalable manufacture of hMSCs in bioreactors where I was the first to demonstrate the litre-scale production of hMSCs on microcarriers in stirred-tank bioreactors.

I am both a Chartered Engineer (CEng) and Chartered Scientist (CSci) and sit on multiple scientific and engineering committees including the IChemE Biochemical Engineering Subject Interest Group, British Standards Institute Biotechnology Committee and the BIA’s Cell and Gene Therapy Advisory Committee.

I have received awards for my research and public engagement activities and in 2020 was recognised as one of the top 20 influential and inspirational individuals in Advanced Medicine by The Medicine Maker listed amongst Nobel Laureates, multi-national CEOs and leading scientists.

Affiliated professional and commercial associations and any perceived or potential conflict of interests:

Professional accreditation

- Chartered Engineer (CEng) (2016- Present)
- Chartered Scientist (CSci) (2016- Present)
- Fellow of the Higher Education Academy (FHEA) (2016-Present)

Membership of Engineering and Scientific Committees

- Member of the Committee British Standards Institute (BSI) Biotechnology Committee (2018-Present)
- Member of the Committee BioIndustry Association Cell & Gene Therapy Advisory Committee (2017-Present)
- Member of the Committee EPSRC Early Career Forum in Manufacturing, (2018-2022)
- Member of the Committee IChemE Biochemical Engineering Subject Interest Group, (2016-Present)

Company Advisory Board and Consulting

- Member of the Scientific Advisory Board ThermoFisher Scientific Cell Therapy (2016-2021)
- Member of the Scientific Advisory Board Biovult Technical, (2016-2022)
- Expert Consultant Quell Therapeutics (UK), Nanoghost (Israel), Pall Life Science (UK/USA), Irvine Scientific (USA), Bio-Cord (Spain), Biovult Technical (UK), Autolus (UK), Aglaris (UK), Sartorius (UK/Germany), Pall Life Science (UK/USA)
- Member of the Committee, BioIndustry Association CGT Advisory Committee (2017-present)

Membership of Professional Bodies

- Member of the Institution of Chemical Engineers (MIChemE) (2016-Present)
- Member of the International Society of Cell and Gene Therapy (2015-Present)

Journals

- Associate Editor Cytotherapy (2019 – Present)
- Reviews Editor and Member of the Executive Editorial Board Biotechnology Letters (2014-Present)
- Guest Editor of two Automation Journal Special Issues and Webinar Moderator, Cell and Gene Therapy Insights
- Member of the Editorial Advisory Board, Cell and Gene Therapy Insights (BioInsights Publishing) (2016-Present)
- Member of the EPSRC Peer Review College (2016-Present)
- PhD external examiner for 10 candidates nationally and internationally
- Peer reviewer >30 journals including Nature Regenerative Medicine and Stem Cells Translational Medicine

Teaching

- Visiting Senior Lecturer Keele University, Aston University (2017 – Present)
- Visiting Lecturer Loughborough University (2015 – Present)

Conferences

- Member of the Organizing Committee, ECI Advancing Manufacture of Cell and Gene Therapies Conference VI and VII, San Diego, USA (2017-Present)
- Member of the Committee, IChemE Biochemical Engineering Subject Interest Group, (2016-Present)
- Member of the Steering Committee, Phacilitate Automation Special Interest Group, (2016-Present)
- Member of the Steering Committee, Advanced Therapies Congress (London) (2019-Present)
- General Secretary, UK Society for Cell Culture Biotechnology (ESACT-UK) (2015-2019)
- Webmaster, UK Society for Cell Culture Biotechnology (ESACT-UK) (2019-Present)

Journals

- Reviews Editor and Member of the Executive Editorial Board Biotechnology Letters (2014-Present)
- Guest Editor of two Automation Journal Special Issues and Webinar Moderator, Cell and Gene Therapy Insights
- Member of the Editorial Advisory Board, Cell and Gene Therapy Insights (BioInsights Publishing) (2016-Present)
- Member of the EPSRC Peer Review College (2016-Present)
- PhD external examiner for 10 candidates nationally and internationally
- Peer reviewer >30 journals including Biochemical Engineering Journal & Biotechnology and Bioengineering, Stem Cells Translational Medicine and Cytotherapy

Teaching

- Programme Director MSc Manufacture and Commercialisation of Stem Cell and Gene Therapies, UCL (2019 – Present)
- Visiting Senior Lecturer Keele University, Aston University (2017 – Present)
- Visiting Lecturer Loughborough University (2015 – Present)

Conferences

- Member of the Organizing Committee, ECI Advancing Manufacture of Cell and Gene Therapies Conference VI, San Diego, USA (2017-Present)
- Member of the Committee, IChemE Biochemical Engineering Subject Interest Group, (2016-Present)
- Member of the Steering Committee, Phacilitate Automation Special Interest Group, (2016-Present)
- General Secretary, UK Society for Cell Culture Biotechnology (ESACT-UK) (2015-Present)

I have no role with fiduciary responsibility with any other professional society/association.

List of top notable contributions to the field (e.g. publications, patents, reports, products advanced to clinical trial or regulatory approval, asset development, mergers, acquisitions, etc.) from the last 10 years:

Paper 1:

Rafiq, Q.A., Hanga, M.P., Heathman, T.R.J., Coopman, K., Nienow, A.W., Williams, D.J., Hewitt, C.J. 2017 Process development of human multipotent stromal cell microcarrier culture using an automated high-throughput microbioreactor. *Biotechnology and Bioengineering*, 114, 2253-2266.

In this publication, we demonstrated and explained in detail, for the first time, the amenability of the automated cell culture microbioreactor system for the development of scalable adherent human mesenchymal stem cell (hMSC) microcarrier culture processes.

The publication has two significant contributions to the field:

1. It demonstrated the successful culture and harvest of human mesenchymal stem cells (hMSCs) on microcarriers in a high-throughput, automated microbioreactor. In the publication, we outlined the methods and adaptations required to enable the system to be employed for microcarrier culture.
2. Importantly, we then demonstrated how the high-throughput, automated microbioreactor system can be used for bioprocess development, resulting in a significant increase in hMSC yield whilst maintaining cell quality; this finding was subsequently validated with larger-scale studies.

This was the first time that an automated, high-throughput microbioreactor was employed successfully for the culture and harvest of an adherent cell type on microcarriers and has significant positive implications for process development of other adherent cell types.

Finally, we demonstrated that moving to a serum-free process in the microbioreactor resulted in improved process consistency and >250% increase in yield compared to the serum-based process.

The findings of this study have significant implications other R&D groups, both academic and industrial as it demonstrates the platform is an effective tool for bioprocess development and that a combination of serum-free medium, control, and automation improves both process yield and consistency.

Paper 2:

Costariol, E., Rotondi, M., Amini, A., Hewitt, C.J., Nienow, A.W., Heathman, T.R.J., Micheletti, M., Rafiq, Q.A. 2019. Establishing the scalable manufacture of primary human T-cells in an automated stirred-tank bioreactor. *Biotechnology and Bioengineering* doi: 10.1002/bit.27088

This publication demonstrates the scalable manufacture of primary human T cells from multiple healthy donors in an automated stirred-tank bioreactor. In this publication, there are two key contributions which will have a significant impact on the sector:

1. It demonstrates that not only can primary human T cells from multiple healthy donors be cultivated in an automated stirred-tank bioreactor system, but that their growth is consistently and significantly better than that in T-flask static culture, with equivalent cell quality.

2. It demonstrates that at progressively higher agitation rates, and thereby higher specific power inputs ($P/M \text{ W.kg}^{-1}$), the higher the final viable T-cell density. We hypothesise that this improvement in final viable cell density is due to the improved ability to suspend the Dynabeads® (required for cell activation) at the higher agitation rates.

This study is the first demonstration of primary T-cell ex vivo manufacture in an automated stirred-tank bioreactor system and the findings have the potential to be applied to multiple other cell candidates for advanced therapy applications.

Paper 3:

Harrison, R.P., Ruck, S. Medcalf, N., Rafiq, Q.A., 2017 Decentralized manufacturing of cell and gene therapies: Overcoming challenges and identifying opportunities. *Cytotherapy*, 19(10), 1140-1151.

In this paper, we examined both the challenges and the opportunities that the shift in business strategy toward decentralized manufacture of cell and gene therapies represents in an effort to maximize the success of adoption.

Decentralized manufacturing has the potential to revolutionize the manufacturing approach and in departing from the traditional centralized model of manufacturing, decentralized manufacturing divides production across sites or geographic regions. However, this paradigm shift imposes significant structural and organisational changes on a business presenting both hidden challenges that must be addressed and opportunities to be embraced.

By profoundly adapting business practices, we proposed that significant advantages can be realized through a democratized value chain, creation of professional-level jobs without geographic restriction to the central hub and a flexibility in response to external pressures and demands.

Summary of involvement with ISCT in the past five years:

I have been a member of ISCT since 2015 and was appointed to the ESP ISCT Committee in 2019 where I took an active role in shaping the Education Project for the committee. I have also served on the ISCT Nominations Committee as the ESP representative in 2020 and 2021.

I have been the Associated Editor for *Cytotherapy*, the Society's journal, since 2019.

I have attended the following Global ISCT meetings since 2014:

- ISCT 2014 (Paris) - I was invited to speak within Irvine Scientific's Session
- ISCT 2017 (London)
- ISCT 2018 (Montreal) - I was invited by Julie Murrell to speak in the automation and bioprocessing session
- ISCT 2019 (Melbourne)

Summary of strategic vision for the Global Society:

I strongly believe in the aims of the ISCT and have personally benefited and witnessed the positive contribution the organisation has made to the advanced therapy sector. My personal perspective is that the Global Society should be seen as the leading society for advanced cell and gene therapies, bringing together scientists, engineers, regulators, clinicians and practitioners to shape the sector and ensure such therapies improve global health and establish a commercially-sustainable industry.

I also feel that as a region, membership and European ISCT activity should reflect the increasing growth of the CGT sector within the region.

If appointed to the role of Regional VP-Elect for Europe, my contributions would include (above those outlined in the Regional VP-Elect Role Description):

- Develop strategies to increase membership within the European region and provide necessary support to members within Europe. Such strategies would include identifying and engaging with under-represented regions, as well as encouraging ESPs across Europe to engage closely with ISCT EU, outlining benefits and networking opportunities.
- Promote the activities of ISCT and that of the ISCT EU region to collaborators and industrialists across a range of fields connected to advanced therapy.
- Use my social media network as well as the UCL Department of Biochemical Engineering's social media channels to promote the ISCT EU activities.
- Encourage active engagement with industry/commercial partners, particularly early-career researchers in these organisations to be members of ISCT EU, outlining the benefits of having an independent network to aid career development.
- Work with other EU communities that align with the aims and goals of ISCT, including EBMT, ESACT and ESGCT.