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Additive Manufacturing Applied to Authentic - Industry Micro-Fluidic Systems for DNA Sequencing: A product realization experience at the community college level

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Dimitri is an Assistant Professor at Queensborough Community College (CUNY) and has a strong interests in Hybrid learning, leveraging instructional technology (lightBoard) Flipped Class Room Learning, and Online Student-Centered Pedagogy. He is a strong advocate of authentic industry student experiential learning, for making students job-ready upon graduating. Recently, Dimitri has undertaken an a strong interest in the interdisciplinary field of micro-fluidics, and instructional design for LightBoard lesson delivery.

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John Migniuolo received his BSME from Manhattan College (Riverdale, NY) , and has extensive industry experience in the design and development of thermal-fluidic-pneumatic system designs and components during his 25 year tenure in automated medical diagnostic instruments and ultra-centrifuges for vaccine production. Consulting to domestic and international corporations in industries such as IVD/biotech and analytical instrumentation, water quality instruments, beverage dispensing/inline carbonation systems, and other medical fluidic processing systems. The vast majority of his experience has been in the development of automated medical diagnostic instruments within a fully FDA/cGMP/ISO regulated environment, working for Fortune 500 companies such as Bayer HealthCare now Siemens Healthineers where he was instrumental in realizing systems such as the Immuno-1, Opera, and Advia product family, receiving technical achievement awards for his innovative solutions on these product lines. Mr. Migniuolo operates as a recognized expert industry consultant helping start-ups, and established bio-fluidic companies augment their system designs, with emphasis on innovation, reliability, cost control, system forensics and full design services as executive director.

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Additive Manufacturing Applied to Authentic Industry, Micro-Fluidic Systems for DNA Sequencing : A Community College Product Realization Case Study

ABSTRACT

Today's technology demands higher education institutions prepare engineers with the industry skill-sets that more closely aligned to the rapidly evolving needs of the technology sector. As is well known, professional, interdisciplinary, and critical thinking skills developed under authentic-industry learning experiences make for a highly preferred and desired job candidate.

In this paper, we present a mixed-method, undergraduate research case study for an authentic-industry, product development experience with two main objectives: To determine the viability of using additive manufacturing (AM) to produce a 32-channel parallel microfluidic dispenser--a critical component in DNA sample preparation, and to develop student professional and business soft skills leveraging our working platform with our industry partners. A third objective was to create an outreach effort to raise awareness of the bio-technology sector as a viable employment sector for traditional engineering majors (i.e., electrical , mechanical , computer science)---a sector often overlooked by engineering career counsellors. Our outreach effort consisted of a demo showcase of a robotic microfluidic liquid handler, which although was outside the scope of this study, was supported by our industry partners.

From Fall 2019 to Spring 2020, we surveyed N=49 students across three different classes (Thermodynamics, AC circuits, and Control Systems) to first build awareness of the DNA instrumentation industry. Selected students then participated in our yearly Undergraduate Research Program, which faculty designed as an 8-week authentic product development effort our industry partners.

Student performance outcomes (project deliverables) included successful 3D print verification of our 32-channel dispenser design, raising awareness and self-attitude of biotechnology by 55 % and 65% respectively. Through periodic interviews, reflective expositions, industry engineer's feedback, and a final program presentation to the UR committee, we highlight the developmental gains in personal, professional and technical skills areas. Increases in student's self-confidence and efficacy created a feeling of being job-ready, and provided a better understanding of their future career direction. Reflections and faculty observations, indicated a heighten appreciation for interdisciplinary skills and improved soft-skills, indispensable in today's graduating engineers.

INTRODUCTION

As industry-experienced faculty, we focused on partnering with related industry for this experimental development study in bio-liquid handler systems. Bio-liquid handler systems are critical systems used in the highly-relevant field of DNA sequencing and in In-Vitro Diagnostics (IVD), where IVD captures all clinical hematology analysis related to human blood testing.

There were two primary research objectives in the case study: The first was to demonstrate the viability of 3D printing to produce a production grade, 32-channel (i.e., 32 fluidic paths) microfluidic dispenser and wash plate assembly. The second was to help develop personal and professional skills. The high channel count dispensers are critical components for maintaining DNA sample purity and avoiding cross contamination as the sample is shuttled from station to station, dispensing and aspirating precise (micro-liter) amounts of chemical and biofluids. Moreover, fluidic handling is the bottleneck for production through-put in large scale DNA sequencing and IVD systems. The research question: **"Is it possible to provide a valuable learning experience through a faculty-initiated, authentic-industry product development effort in an undergraduate research program in a community college?"** Two-year community colleges have very limited co-op / internship opportunities compared to 4-year schools.

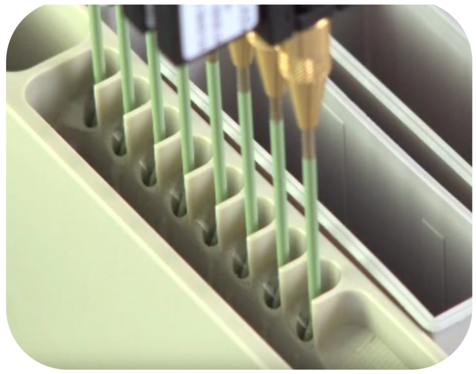

Figure 1. Example of an 8-channel dispenser using high precision nozzles

Success of any authentic industry experience requires careful planning before and during execution of the cycle and perceived authenticity. We chose judiciously narrowing the traditional development cycle to the core functions that would facilitate natural professional and experiential learning commensurate with Bloom's and Kolb's learning models. Our second research question: **"Does an authentic experiential immersive setting help develop professional skills, interdisciplinary skills and help enhance job readiness "**

The experience culminated in two customer deliverables with real deadlines: a 5-minute presentation to the UR Research committee and delivery of the 3D printed hardware to our industry partner/consultant. The UR deliverable took the form of a business-like presentation (not academic report) and include topics such as business case, market drivers, design results, reliability, value selling, and finally, student professional and technical skill gains. As we progressed in our development, we unofficially expanded our scope to develop an automated robotic fluidic handling system with donations by four partnering companies. This demo would add diversity to our traditional robotics club and serve as motivation during student orientation days.

Life Science Industry Background

After the monumental discovery of mapping the human genome (Human Genome Project (HGP) in 2003 [1]) , driving new technologies to advanced discovery was a key objective, as well as studying the impact of genomics on society [2]. Specifically, the Genome Technology Program, focused on new next generation technologies to enable rapid, low-cost DNA Sequencing [3]. As shown in Figure 2, the progress in cost reduction per DNA sequence run has precipitously dropped to just under $1,000, lowering the barrier to entry for other retail genealogy studies (23 & Me).

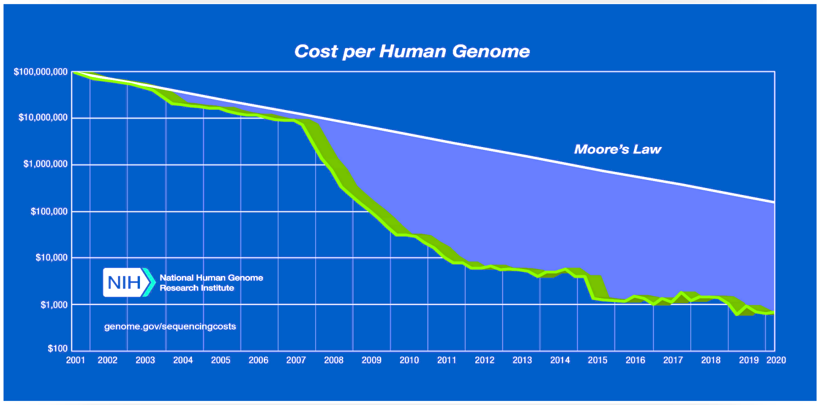

Figure 2. Changes in cost per DNA sequencing run over 20 years

Microfluidics

Richard Feynman said **"There is plenty of room at the bottom"** [4], emphasizing the yet unthinkable possibilities of ultra-small devices which now have been realized in nanotechnology, optoelectronics, and in microfluidics. Microfluidics refers to the precise control of minute amounts of chemical and bio fluids (2–20 µL where the smaller the test sample, the less reagents required which enables parallel processing. The fluidic handling system is a complex array of dispensers, microvalves, micropumps, heaters, pressure and flow instrumentation, and be automated or human operated.

LITERATURE REVIEW

Background

The past decade has seen the explosive growth in microfluidics technology, with US spending on Fluidics alone is predicted reach $23B 2022 from the current $9B in 2018 [5]. Nonetheless, the Department of Labor (DOL) estimates the Biotechnology workforce growth of 5.8%, a value above the national average for engineering and engineering technologists.

Biotechnology's interdisciplinary nature demands biotech professionals to be well-versed in multiple STEM areas including biology, chemistry, environmental science, physics, and engineering which is unrealistic to achieve in 2-year or 4-year higher education. Nonetheless, employers prioritize candidates with hands-on lab experience, or more preferably, those with industrial experience related to professional skills and product development exposure gained during schooling. Hence, schools are under pressure to provide students with the employability skills for career development and lifelong learning [6]**.** Moreover, an IEEE report titled "Designing a career in biomedical engineering" [7] highlights the importance of interdisciplinary skills in the workplace and asks "what major should I choose" to enter the bioengineering field. As indicated in Figure 3, two educational paths can serve the biotechnology sector, Path B which according to our industry partners is heavily overlooked and not discussed, making engineers in this area scarce and in-demand.

They state that traditional core engineers have the foundational skills, and students should be aware that being in a biomedical program is not a requirement for entering this field. They also state that "…opportunities are greatest for students with industry or clinical design experience**"**, which is one on reason we choose to perform this project.

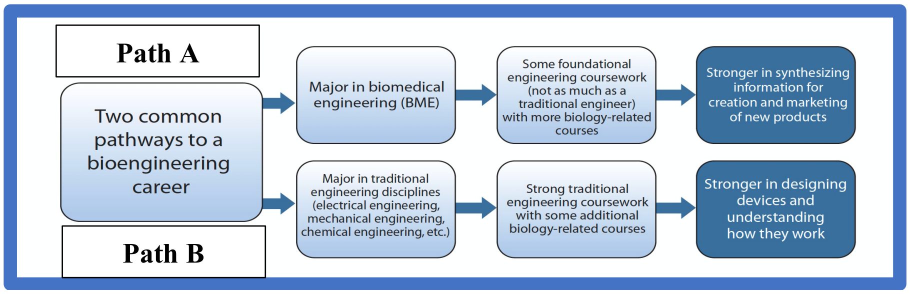

Figure 3. Two educational paths to a bio-engineering career

The goal of our project was to provide a framework for an authentic industry experience in the UR program to enhance experiential learning because industries have been frustrated with the lack of preparedness of graduates to enter the professional realm of engineering. Furthermore, in a recent study by Deloitte, the authors reported that professional skills (soft skills) are highly valued and necessary for the evolving technology and business worlds.

Nonetheless, in community colleges, co-op or industry internships are difficult to come by given the short two-year curriculum. To address the well-known gap in industry skill sets, a Fall 2016 report titled "The Skill and Competencies Needed for In-Demand, Entry level Tech jobs in New York City" [8] states that the two of the top five sought after skills are:

- Demonstration of technical skills in a "real world" setting; and
- Students' ability to identify essential requirements to solve problems based on users, stakeholders, customers, and realistic constraints.

Recognizing the genuine benefits of real-life industry exposure, CUNY has responded to these findings with a limited series of grants **[9]** across its 17 schools to motivate faculty to implement such industrial learning in new and existing coursework. Although these efforts are commendable, they occur in small step initiatives, are limited in deployment, scalability, and continuity.

METHODOLOGY

Professional and Interdisciplinary Skills
We took an initial qualification assessment and social personality inventory of our student prior to his selection to ensure he was well matched for this type of learning. Matching students to the job setting, is a kay factor to any authentic experiential settings.

Each product development stage, our planning objectives and outcomes were discussed with our engineer-in-training to assure a strong sense of closeness and trust, to set expectations, and that student input was welcomed and needed. For professional and interdisciplinary skills development, we developed close interaction scenarios with real industry workers across electrical and mechanical engineering departments and via role-playing at select times with our own staff. For example, " What would you do if the electrical controller design person said he was too busy to help you?"

Meetings with application engineers, sales managers, and marketing managers, across four companies provided ample interdisciplinary exposure and the student was encouraged to question staff during the meeting which often exceed the scheduled end time.

Surveys and Participants

Phase 1: The first round of surveys was given as an exploratory exercise to determine the baseline level of DNA / Biotechnology awareness and attitudes to Thermodynamics and AC Circuit theory students during the tempestuous COVID times in Fall 2019 with a total of 27 respondents at 85% response rate.

The survey was repeated two weeks later after a 30-minute talk on R&D DNA projects and high-end engineering jobs being offered , sharing active community outreach awareness programs [10] followed by a total of 1.5 hours of short 5-10 minute**,** multi-theme videos, including high resolutions Jove video sources on the potential of curing power of DNA studies.

Phase 2: We ran survey in Fall 2020 , before and after training in a Feedback Control course with 19 of 23 students. The students were shortlisted to 3 students by GPA (min 3.0) , demonstrated strong interest and survey questions related to agreement in having technology better serve man-kind over profit. Later interviews (45 minutes) conducted technical ability, time commitment (no outside work conflicts), motivation, enthusiasm, dependability, and willingness to learn with little or no direction---as a question. Index of Learning Style (ILS) [11] where lastly given to identify any unusual bias in learning styles.

The survey instrument was a modified SALG (Student Assessment Learning Gain), which has a long history of periodic validity evaluations. The instrument is known for capturing student self-awareness of, self-attitude in, and motivation to, self-assessment of their own learning gains or measured gains in learning new technologies. [12]

3D printing viability

Demonstrating 3D printing as a viable and robust method to produce micro-fluidic products of high channel count, would evolve its use as a tool to verify various designs not just a production tool. The tangible outcomes anticipated from a positive result would:

- Increased intellectual know-how for more advanced designs possible serving other industry sectors in life sciences unrelated to DNA and IVD.
- Validate the known rapid prototyping time advantage and shorten proof of concept cycles in this physical dimensional range which may open valuable research projects studies involving UV power and exposure times.
- Increase proprietary know how minimum dimensional process capability and possibly open further research to overcoming the limitations found.

Final Internal Deliverable

The final deliverable to the UR committee was a 5-minute presentation covering the project's 8+ week effort presented by our engineer, and served as final assessment of our official project close-out. In stark contrast to typical academic research presentations, we ensured business-like presentation format to drive our reporting scheme. The presentation followed industrial style context to show the students had learned many interdisciplinary skills in technical areas beyond his normal schooling. A business-centric rubric was used to evaluate the content of presentation, its delivery, and overall professional communication tone during the dry runs which served as training and instruction.

RESULTS

Phase-one survey results revealed the expected increase in self-awareness after post training on the DNA sector and included self-attitude questions, since attitude is linked to self-image---an important item in developing professional skills. Figure 4 shows **a subset** of the total questions, where Q1, Q3 and Q5 were statistically significant at P(< 0.01) and P(< 0.001) levels. Average scores show 48% increases in awareness and a surprising score on the humanitarian concern for technology to serve the "good of society". In Q3, improvements in self- perceived technical ability was noted in EE students over the MEs.

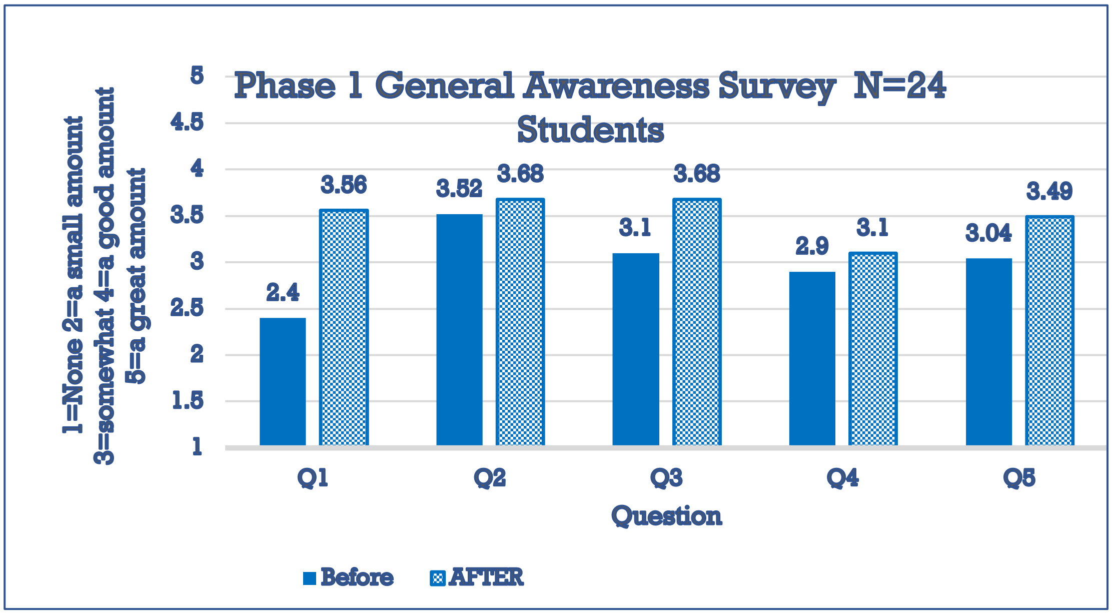

Figure 4. Show average scores with improved DNA Technology Self-Awareness

*Q1**= Interested in the DNA Bio Tech Fields** (P< 0.001)*
Q2= Interested in societal and ethical issues (medical and health applications)
*Q3=** Confident in my ability to understand scientific and engineering concepts*
Q4= Comfortable asking for help from others (professor, peers, TAs)
*Q5**= Interested in collaborating with peers from different Eng. Majors*

Phase 2 Survey Results

The Fall 2020 semester students were surveyed for the same reason, to quantify scores in self-awareness. However, for this case, we were to select our UR candidate from our process review. Table 1 depicts the large gain in self-awareness and is documented in Appendix D .

3D Printing Results

The Stratasys 750 was used as we wanted to ensure visibility of flow in the flow paths of the finished product. The Poly-Jet UV method , using Vero-Clear 875 material, deposits additive layers via ink jet sprays at 18 μm per layer and is suited for highly complex shapes with delicate features, such as the fluidic network paths on our wash plate assembly (0.050 in ID). Some anticipated design adjustments were introduced such as increased UV build cure time (cure times in between depositions) along with revised part orientation from our first run. Our first run developed static fatigue cracking after three 3 weeks in the cylinders of the wash plate assembly. It's been our experience that for medical applications subject to harsh chemicals, a 24-hour post build UV cure is standard. APPENDIX A shows the completed Wash / Well Plate and dispenser as 3D Printed. Figure 5 shows the 32-channel manifold fitted precision polyether-ketone (PEEK) dispensing nozzles (as opposed to pipettes).

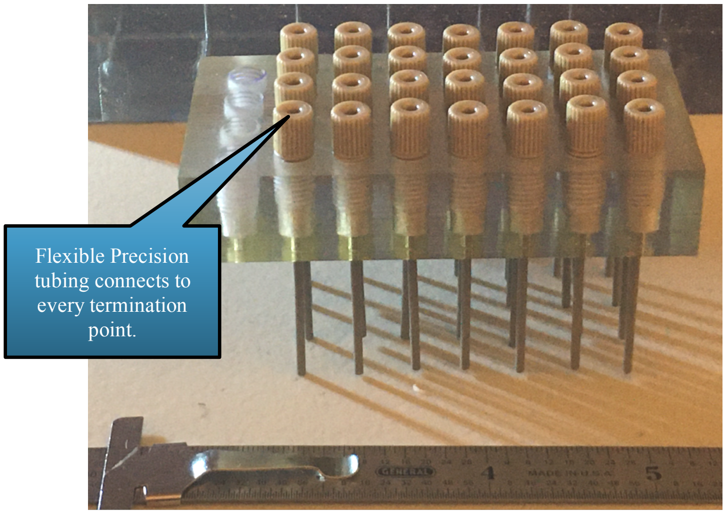

Figure 5. 32 Channel Dispenser with PEEK Nozzles

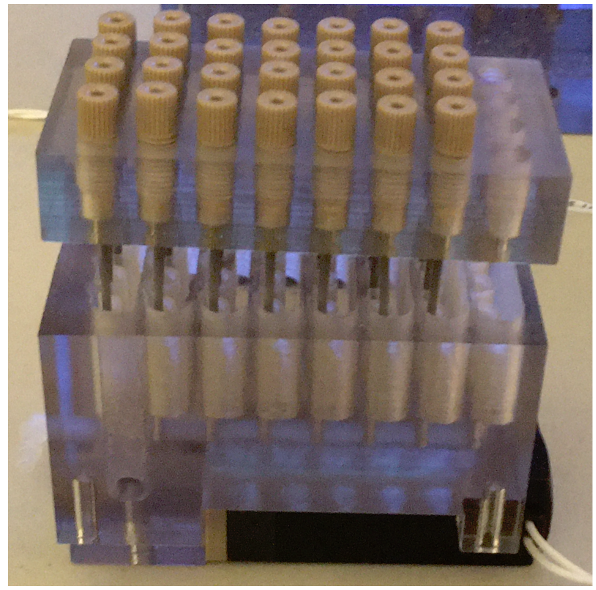

Figure 6. Assembled Channel Dispenser with Wash Plate Assembly.

Later, our student wrote his reflections on what was learned about himself as a team member, as an individual (growth in self-awareness), and his thoughts about the personalities and communication skills used for each meeting, reflecting this development over time. Based on these findings we could determine the progress in professional and interdisciplinary skills as evidence from Reflection notes, oral discussions, interviews, of our research objective.

Figure 7 provides a close up of the fluid channel network. All parts required manual hole tapping and fluid channel paths were air blasted to ensure no residual loose debris blockage. This was followed by a liquid flush for completeness.

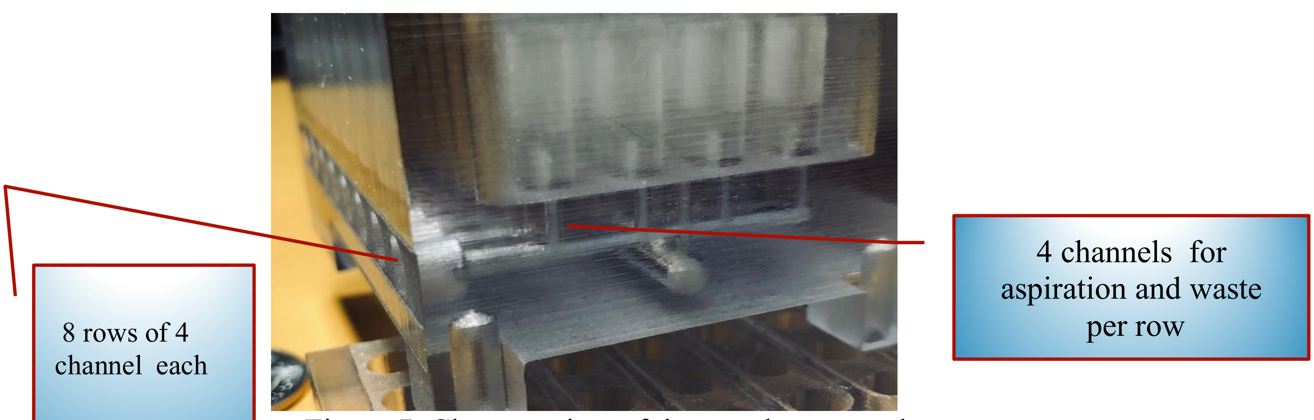

Figure 7. Close up view of the translucent wash plate assembly showing the network of fluid paths

Discussions
The professional and interdisciplinary skills were monitored during a role play sessions. The experiential immersive learning (retention) was assessed via oral questioning and reflective exposition. recorded.
Encouraged by our intentional close relationship as mentor and mentee as well as our professional relationship as program manager and hired engineer, the student was closely bonded and support, exhibited a strong appreciation for requirements definition, challenging legacy requirements for the design of the nozzle and Wash Assembly. Assessments comprised various mini design reviews, and industry representative observances. Based on student feedback, we observed that students had a strong appreciation of interdisciplinary skills, which were obtained through 3D printing, selection criteria for micro pumps, coding of the automated robot to be used in the automated fluidic handling showcase demo, chemical compatibility via similarity analysis, understanding of market drivers, and the technical understanding of the elements that guide precision in microfluidics, namely the micro pump displacement accuracy.

The technical ability was demonstrated by student's knowledge of the high-level requirements for 32-channel nozzle design, and understanding that precision all starts with the micro-pump specifications such as Dispense Volumes (μL): 1 – 50, Accuracy: ~ 99.5%, Precision: < 0.2% CV, followed by mechanical properties of the connecting tubing captured by durometer rating, elongation and compression before and after thermal aging for 70 hr. at 350 deg F. Assessments were observational interviews oral discussions. The overall student development can be tracked by task which follow Bloom's Taxonomy below in Figure 8:

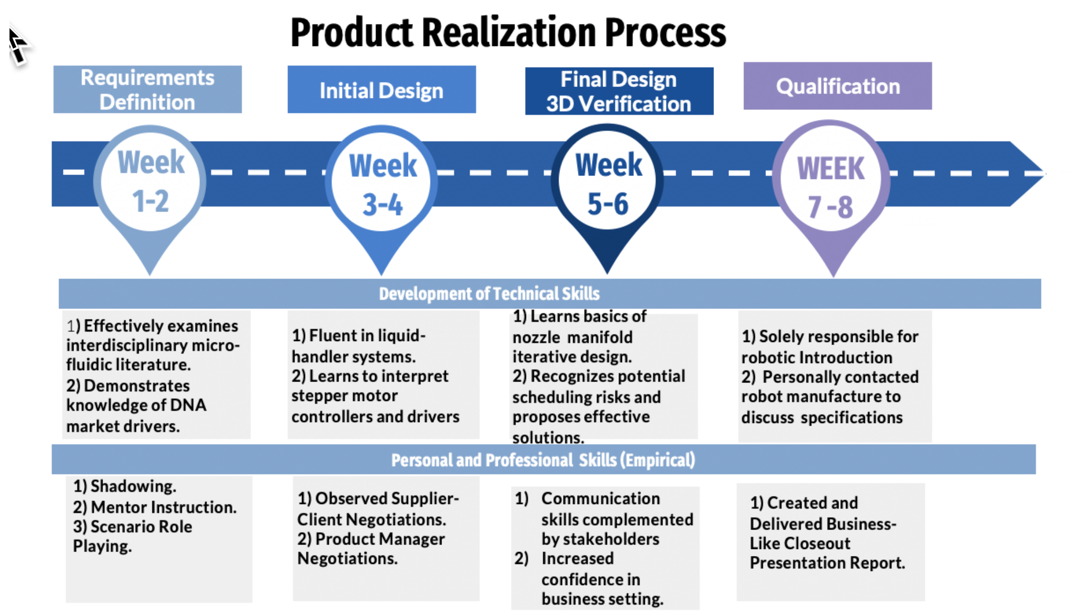

Figure 8. Overall Student Development by level of task completion

CONCLUSIONS

Performing authentic industry work in a Community College has separate challenges and hurdles that requires careful planning prior to start of the project due to limited time with the student, and should be planned not to be overly comprehensive in any development process area. The goal is to stimulate a positive experience and generate motivation where the student can embrace and understand the enhancement to their professional and technical skill sets, and possibly adjust career goal direction.

Based on our two research questions and the methodology findings from the interviews and questionnaire from Phase The experiential portion of this authentic product design was a very positive experience. Student motivation and learning experiences were observed in periodic interviews during the 8-week effort revealing positive results in the awareness, professional skills, and interdisciplinary skill development. The positive attitude is what drove the extension of project to include a robotic demo of the bio-liquid handler systems.

This case study points to the value of using experimental learning practices to develop professional skills, technical skills, and personal growth. This was a difficult project and required dedicated students with innate technical skills, and a sense of urgency to being with. Going into this project, the faculty was fully aware of this and eliminated the details of project management. Authentic experiential in an industry setting created a strong sense of ownership to the student, a quality which will stay with them all their lives. Additive manufacturing should not be looked at as process for making, but use as a creative tool to realize solutions.

Industry Donation Acknowledgements

This research work in product development in micro-fluidic Handler systems would not have been possible. Generous equipment, parts and labor are profoundly appreciative as we extend our thanks to the following companies:

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Burkert Life Science Microfluidics Group
Tony Wojczak - Area Sales Manager –Microfluidics
Donated: Vacuum Waste Valve

Diba - BioChem Fluidics
Chris Withrow - Director of Sales
Antonio Mendes – Senior Applications Engineer
Donated: Precision Piston Pump,
PEEK and Teflon Tubing, Bottle Caps

Parker Hannifin Corporation - Precision Fluidics Division
Kevin Sferro - Sales Manager – Americas
Donated: Diaphragm Pump

Idex Health and Science
Wald Krause – Area Sales Engineer
Component(s) Donated: PEEK Fittings and Teflon Tubing

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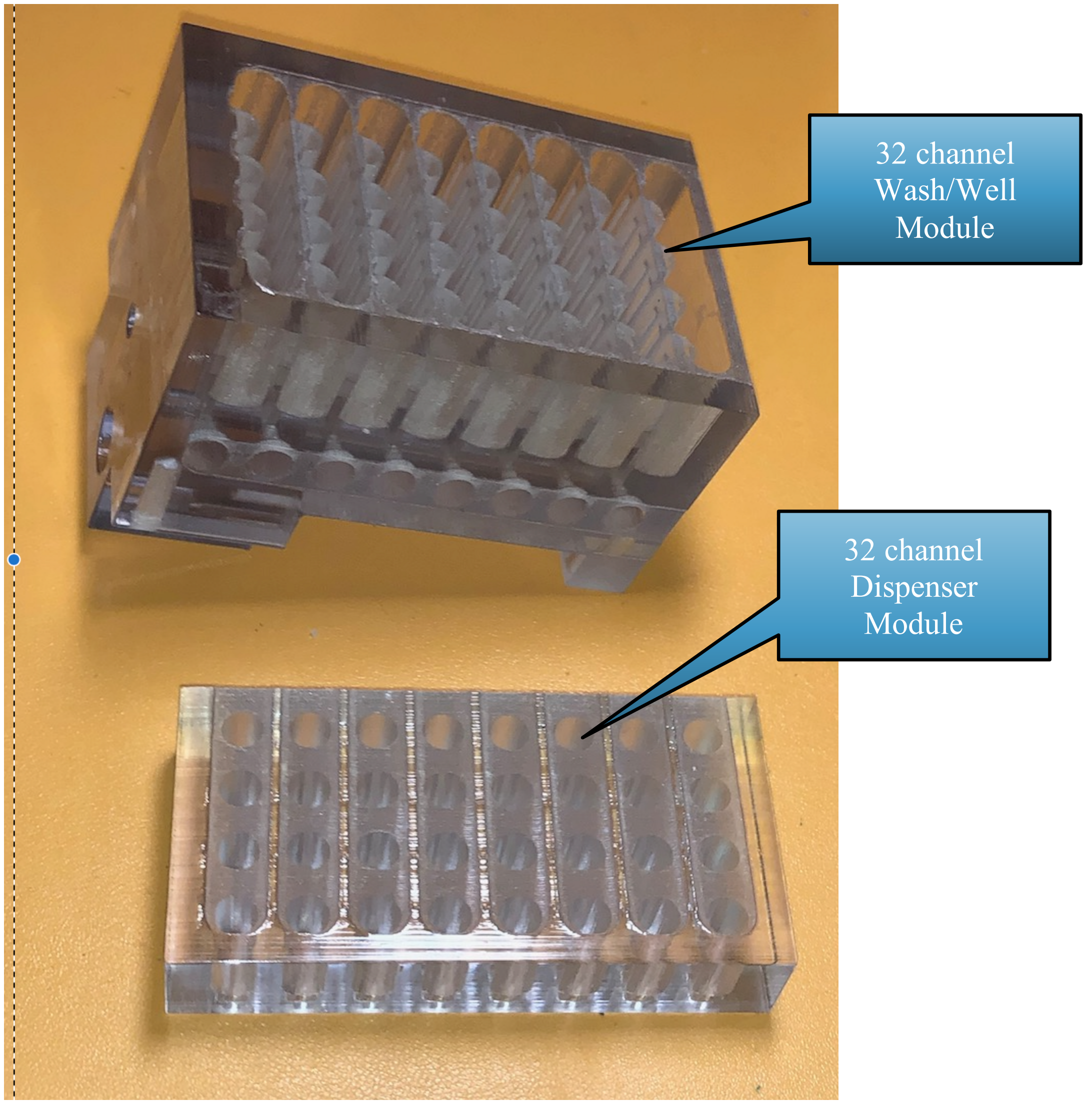
APPENDIX A

3D Printed 32 Channel dispensing module and matching wash/well assembly

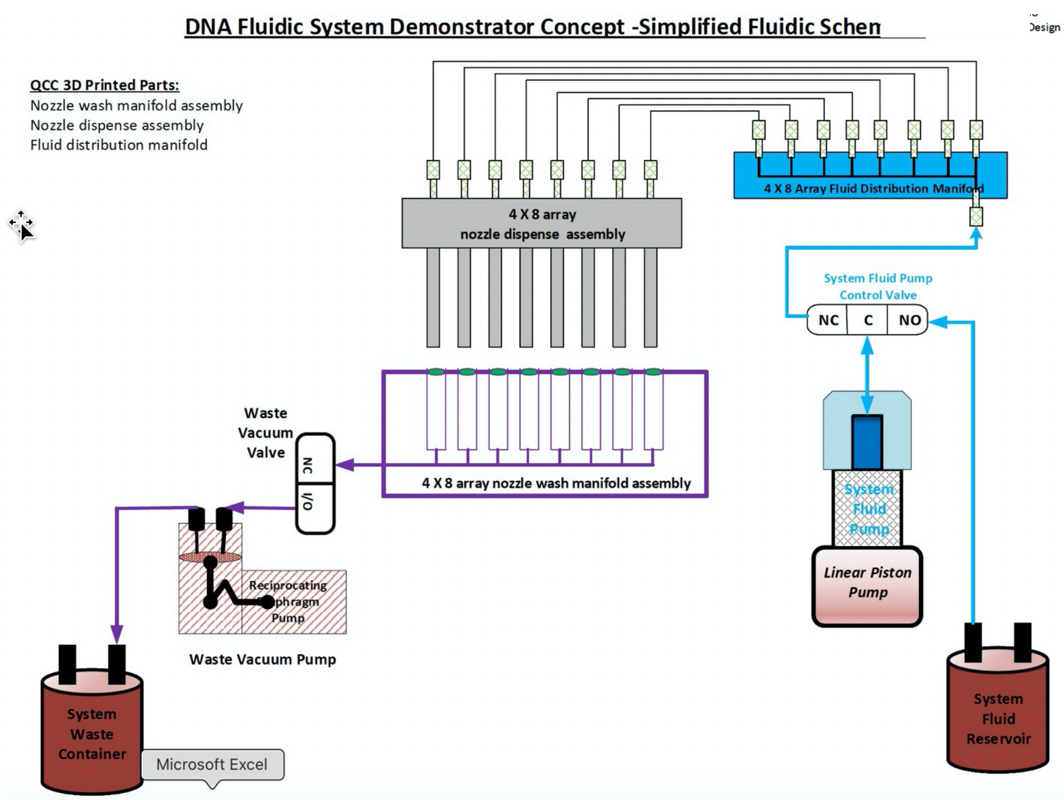


APPENDIX B
Sample of the SALG Instrument Survey
Exposure, Awareness, and Self-Attitudes

Awareness of DNA R&D Industry and Laboratories Job Market

7. How much do you agree or disagree with the following statements?	strongly disagree	disagree	neutral	agree	strongly agree	not applicable
7.1 Human beings will benefit greatly from DNA / Bio Technology works at the molecular level atom by atom to build new structures, materials and machines.	○	○	○	○	○	○
7.2 Our most powerful 21st century technologies (i.e. robotics, genetic engineering, nanotechnology) are threatening to make humans an endangered species.	○	○	○	○	○	○
7.3 DNA Processing is a natural development of human evolution, so it will enhance our survival.	○	○	○	○	○	○
7.4 We should be cautious in the application and use of DNA research so that we do not create conditions that might harm our civilization.	○	○	○	○	○	○
7.5 It is important for scientists and engineers to assess the social, cultural and ethical implications of their work.	○	○	○	○	○	○
7.6 DNA Processing like any other kind of technology is value neutral and can be used both for good or bad purposes.	○	○	○	○	○	○
7.7 The potential benefits of DNA Processing far outweigh the potential for abuse.	○	○	○	○	○	○
7.8 Practical applications of DNA Analysis will enable economic growth with much less of an impact on the Health of the world than today's technologies.	○	○	○	○	○	○
7.9 DNA anlaysis as the potential to create unknown human development problems	○	○	○	○	○	○
7.10 There is a strong demand for workforce as Lab Technicians, Engineers and Project Managers in the Bio-Medical Industry	○	○	○	○	○	○
7.11 Large Companies are making it known to communities and Local 2 and four years schools that there is a shortage of workers	○	○	○	○	○	○
7.12 It is hard to evaluate DNA testing until scientific or engineering advances actually produce some applications which are studied for long-term societal impact.	○	○	○	○	○	○
7.13 It is inevitable that DNA and the genome will have military applications.	○	○	○	○	○	○
7.14 DNA should not be used for military purposes.	○	○	○	○	○	○
7.15 New DNA Results will benefit normal everyday life	○	○	○	○	○	○

APPENDIX C
Design of the Demo Unit of the Automated Liquid Handler



APPENDIX D

Table 1. Phase 2 DNA Industry Student Awareness Results

Fall 2020 SALG Survey to Control Systems Class N=19 1=None 2=a little amount 3= a small 4=good amount 5=great amount		Average (Gain) **N=19**		P(< 0.01)
		Before	After	
Q1 Human beings will benefit greatly from DNA / Bio Technology work	**1**	**2.95**	**3.65**	Y
Q2 DNA Sciences is a development of human evolution, so it will enhance our survival	**2**	**2.46**	**3.33**	Y
Q3 We need caution in DNA applications to avoid harm our civilization	**3**	**2.81**	**3.15**	Y
Q4 The potential benefits of DNA Processing far outweigh the potential for abuse	**4**	**2.73**	**3.67**	Y
Q5 DNA analysis has the potential to create unknown human development problems	**5**	**2.2**	**3.75**	Y
Q6 There is a large workforce demand in bio-fluid handling systems for technicians, engineers and PM's	**6**	**3.1**	**4.12**	Y
Q7 Untreatable permanent diseases and injuries could be cured by advances in DNA cures	**7**	**2.7**	**4.5**	Y
Q8. Bio-medical sector ready for explosive growth; needs workforce Tech and Eng	**8**	**2.31**	**3.52**	Y