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คู่มือในการถ่ายทอดเทคโนโลยี (Technology Transfer Guide Line)

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Rev.	Released date	Approval Ref.	Originator	History
01			Jidapha S.	Initial Release

1. PURPOSE

This document is provided and established to be guide line for technology transfer process in New Product Introduction (NPI) project which covers both of new customer and existing customer in terms of new manufacturing process design and development.

2. SCOPE

This document is applied to all products of X Business Unit which have technology transfer in the production line.

3. RESPONSIBILITIES/AUTHORITIES

3.1 Product Team Leader/ Product manager

- Responsible for leading and establishing the NPI/ Engineering team member for transferring new product/ technology coming
- Responsible for organizing the NPI/ Engineering team structure, manufacturing, engineering, quality, purchasing and material control as appropriate.
- Responsible for overseeing the planning process and reviews the progress of transfer plan.
- Responsible for assuring the First Article (FA) report, which shall be completed, and approved by customer.
- Responsible for review and managing impact of change such as inventory, status, disposition plan, process, related document and provide action plan.

3.2 NPI/ Engineering Team

Responsible for supporting organization to achieve targets and plans by following this document.

3.2.1 Process/ Product/ Test/ Failure Analysis Engineer

- To assure that test program, golden units and any required are available and ready based on transfer date.
- To follow up if customer qualification is required.
- Responsible for generating and completing the FA report including the completion of approved FA report.
- Responsible for providing the Process Flow and Work Instruction.
- Responsible for training the production operator per Process Flow and Work Instruction.

3.2.2 Quality Engineer

- Responsible for assuring the transfer product and process are followed by this document and customer requirement.

3.2.3 Bill of Material Engineer

- To review and verify new item and cooperate with NPI/ Engineering team to complete all data and consolidate data in order to send them to upload Bill of Material (BOM) into Oracle database.

3.2.4 Maintenance Engineer

- To conduct equipment verification and qualification.

3.2.5 Planner

- To set up new part number and routing in oracle system.
- To review the material shortage and follow up for achieving the production plan.
- To follow up on schedule of deliveries of modules in order to meet 1st order

3.2.6 Buyer

- To identify and order the required raw materials for production.

3.2.7 Manufacturing Supervisor

- To responsible on any manufacturing activities in the production line.
- To responsible for supervising the implementation of process control and perform the Corrective Action (CA) in case of discrepancy was found in production area.

3.3 Production Operator

- Responsible for performing per work instruction.

3.4 Quality Control Staff/ Assessor

- To responsible for performing the audit and issue DAR (Discrepancy Action Request) in case of discrepancy was found in production.

4. REFERENCE DOCUMENTS

QP-ENG-005	New Product Introduction
QP-QE-002	Corrective Action and Preventive Action
QP-IPQC-002	Discrepancy Action Request

5. DEFINITIONS/ABBREVIATIONS

Customer	Original Equipment Manufacturers
Term of Technology transferred	Including terms of product, machine and equipment, process, knowledge and know-how, software and program drawing, fixture, tester.
NPI	New Product Introduction
FA report	First Article Report
WI	Work Instruction
BOM	Bill of Material
CA	Corrective action
PA	Preventive action
DAR	Discrepancy Action Request

Mfg	Manufacturing
PE	Process Engineer
QC	Quality Control
QE	Quality Engineer
P/N	Part Number
QP	Quality Procedure
EEIF	Engineering Experiment for Improvement Failure
ME	Maintenance Engineer
ECN	Engineering Change Notice
DCC	Document Control Center
SQE	Supplier Quality Engineer

6. SAFETY

N/A

7. EQUIPMENT AND SUPPLIES

Product/ Technology Transfer Check List

8. WORK STATION READINESS CHECK

N/A

9. PROCEDURE

9.1 PRE-PROCESSING INSPECTION

N/A

9.2 WORKING PROCEDURE

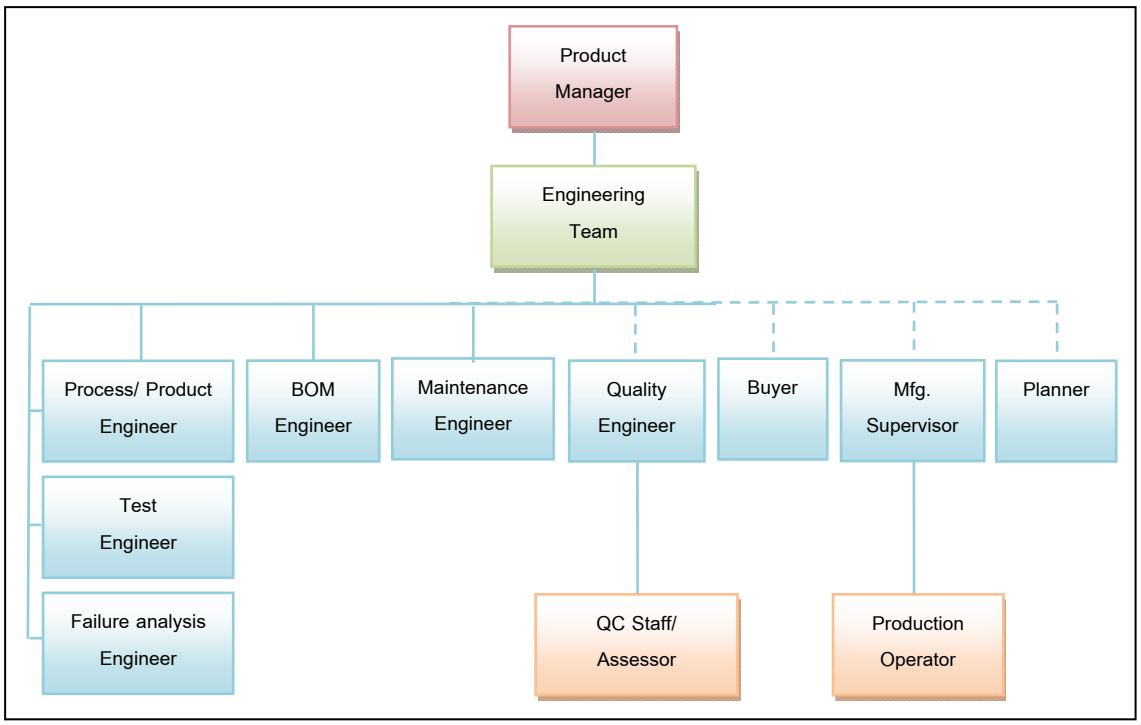
The working procedure consists of three sections:

- Team Structure and Assignment
- Product/ Technology Transfer Process
- Product/ Technology Transfer Check List

9.2.1 Team Structure and Assignment

Product Team Leader/ Product manager is responsible to lead and establish the NPI/ Engineering team member for transferring new product/ technology coming and should list all NPI/ Engineering team members as well as define his/ her role and responsibility.

NPI/ Engineering Team Structure



Team assignment

Team Members	Role and Responsibility.
Product Team Leader/ Product manager	■ Responsible for leading and establishing the NPI/ Engineering team member for transferring new product/ technology coming ■ Responsible for organizing the NPI/ Engineering team structure, manufacturing, engineering, quality, purchasing and material control as appropriate. ■ Responsible for overseeing the planning process and reviews the progress of transfer plan. ■ Responsible for assuring the First Article (FA) report, which shall be completed, and approved by customer. ■ Responsible for review and managing impact of change such as inventory, status, disposition plan, process, related document and provide action plan.
Process/ Product/ Test/ Failure Analysis Engineer	■ To assure that test program, golden units and any required are available and ready based on transfer date. ■ To follow up if customer qualification is required. ■ Responsible for generating and completing the FA report including the completion of approved FA. ■ Responsible for providing the Process Flow and Work Instruction. ■ Responsible for training the production operator per Process Flow and Work Instruction.
Quality Engineer	■ Responsible for assuring the transfer product and process are followed by this document and customer requirement.
Bill of Material Engineer	■ To review and verify new item and cooperate with NPI/ Engineering team to complete all data and consolidate data in order to send them to upload Bill of Material (BOM) into Oracle database.
Maintenance Engineer	■ To conduct equipment verification and qualification.
Planner	■ To set up new part number and routing in oracle system. ■ To review the material shortage and follow up for achieving the production plan. ■ To follow up on schedule of deliveries of modules in order to meet 1st order
Buyer	■ To identify and order the required raw materials for production.

Team Members	Role and Responsibility.
Manufacturing Supervisor	■ To responsible on any manufacturing activities in the production line. ■ To responsible for supervising the implementation of process control and perform the Corrective Action (CA) in case of discrepancy was found in production area.
Production Operator	■ Responsible for performing per work instruction.
Quality Control Staff/ Assessor	■ To responsible for performing the audit and issue DAR (Discrepancy Action Request) in case of discrepancy was found in production.

9.2.2 Product/ Technology Transfer Process

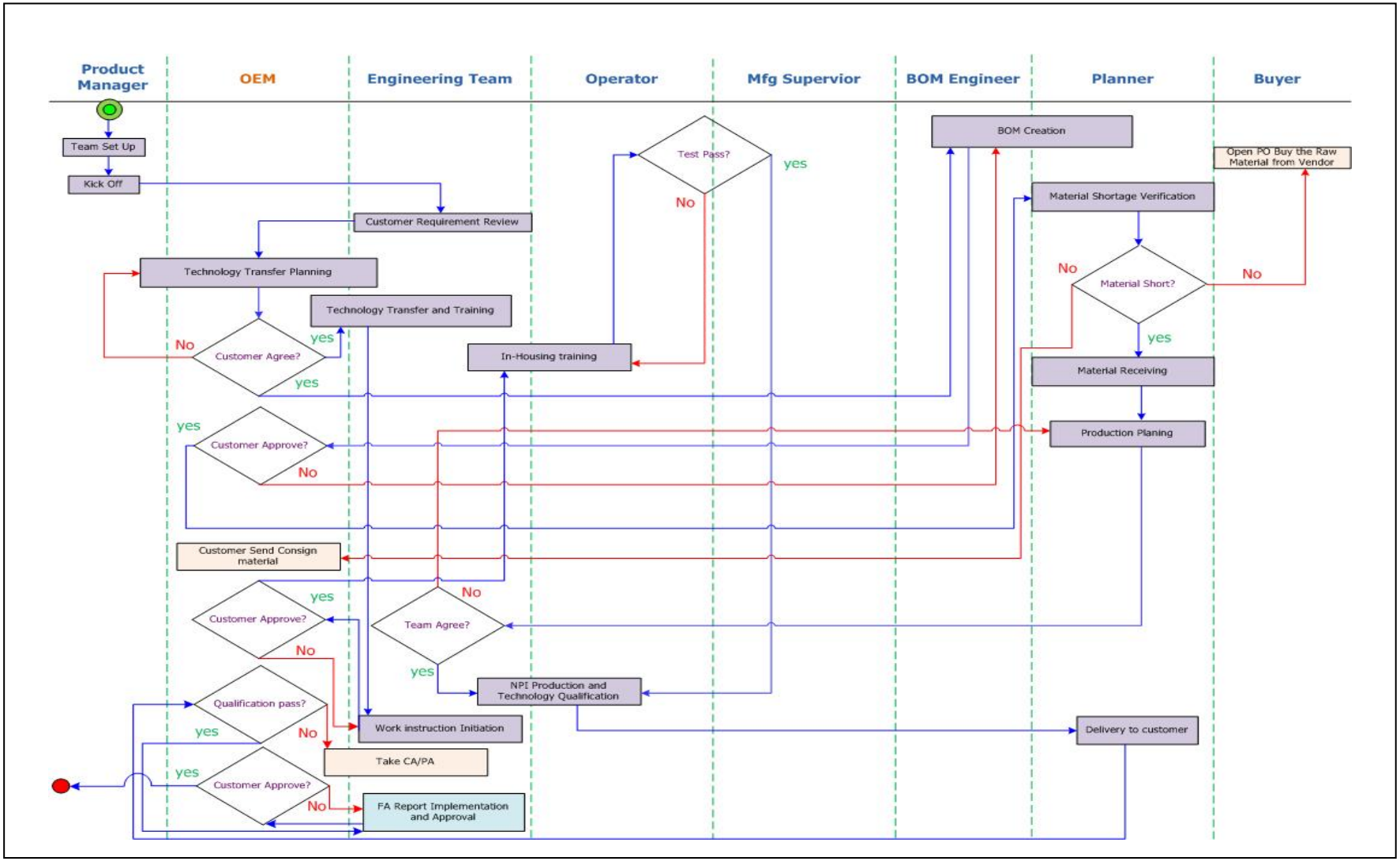
NPI/ Engineering team members follow this Product/ Technology transfer process as following which is identified of method, action item, responsibility, media output and problem solving & disposition.

1. Product/ Technology Transfer Kick Off
2. Customer Requirement review and Feasibility Study
3. Products/ Technology Transfer Planning
4. BOM Creation
5. Material Shortage Verification
6. Material Receiving
7. Production Planning
8. Product/ Technology transfer and Training
9. Work Instruction/ Visual Aid/ Check List Initiation
10. In-House Training and Examination
11. NPI Production/ Technology Qualification
12. Delivery
13. First Article Report Implementation and Approval

9.3 POST-PROCESSING INSPECTION

N/A

Product/ Technology Transfer Process Flow Chart



No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
1	Product/ Technology Transfer Kick Off	■ Collect the relevant information to prepare the transfer plan ■ Distribute the project plan to all team members ■ Set up the meeting to assign the role and responsibility of each team members	Product manager	After setting Engineering team member	Customer requirement, Email , Meeting	Minute meeting	■ If need more information, shall ask it from customer.	■ Team awareness
2	Customer Requirement review and Feasibility Study	■ Engineering team should receive the data of customer input s which are related to the requirement of manufacturing and transfer process ■ Review the customer input s which can be separated to “NPI” and EEIF project ■ Study for the feasibility of transferring ■ Set up the transfer plan	Engineering team	After getting customer requirement	EEIF document, Email	Transfer plan	■ If need more information, shall ask it from customer. ■ If any problems occur, the CA and PA will be taken by using error-proofing method.	■ Team awareness ■ Product cost
3	Product/ Technology Transfer Planning	■ Engineering team shall contact customer to review the transfer plan to get agreement ■ Product manager will be lead for set agreement ■ Team members acknowledge for the transfer plan and agreement	Product manager, Engineering team, OEM	After getting the transfer plan or Transferring start date	Conference call, Meeting	Transfer plan and agreement, Minute meeting	■ If customer do not agree, shall review, re-plan and response with customer	■ Team awareness ■ Transfer cost ■ Time used (with in agreement)

No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
4	BOM Creation	■ Planner sets up new part number and routing in oracle system. ■ BOM Engineer reviews and verify new item ■ Create BOM then upload it into Oracle database ■ Upload related document into DCC. ■ Send BOM to customer review and ask approval	Planner, BOM Engineer OEM	After getting customer ECN	Email , Customer database, Oracle database, ECN document	Part number of materials, BOM, Drawings and specifications	■ If need more information, shall ask it from customer. ■ If BOM is not correct, shall review, re-create and response with customer	■ Time usage (>15 days)
5	Material Shortage Verification	■ Review the material shortage and report to customer	Planner, Buyer, OEM	After BOM completed	Email	Material shortage report	■ If material shortage, shall inform customer to provide it. ■ If customer wants us to buy raw material from vendor or there is no consign material from customer, buyer shall open PO for material required.	■ Time usage (>3 days)

No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
6	Material Receiving	■ Follow up material from customer (consign material) or buyer for achieving the production plan ■ Do the material receiving document/ invoice	Planner	After getting invoice	Email, Oracle database	Material	■ If any problems occur, feedback to customer (consign material) or SQE/ Buyer.	■ Time usage (per Material Receiving schedule)
7	Production Planning	■ Planner sets the Production plan and Shipment plan ■ Send the Production plan and Shipment plan to team and Product manager review ■ Set up the meeting to review the production plan and Shipment plan ■ Daily/ Weekly review output	Planner, Engineering team, Product manager,	After getting the production plan or NPI Production start date	Email, Meeting	Production plan and Shipment plan, Minute meeting, Daily/ Weekly report	■ If team do not agree, shall review, re-plan and response with team ■ If any problems occur, the CA and PA will be taken by using error-proofing method.	■ Team awareness ■ Resource usage ■ Time usage (per commitment)
8	Product/ Technology transfer and Training	■ Customer supplies for equipment and machine ■ ME shall set up equipment and machine per customer's instruction or use outsource ■ Customer gives the relate document such as product specification, instruction, etc, ■ Customer trains for new product/ technology on site both theory and practice.	OEM, Maintenance/ Process/ Product/ Test/ Failure Analysis/ Quality Engineer	Follow the transfer plan	Presentation, instruction, Manual, troubleshoot document	Knowledge / and know-how of engineer	■ If there is any query or need more information, shall feedback or ask it from customer.	■ Team awareness ■ Set up cost ■ Time usage ■ Team knowledge

No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
9	Work Instruction/ Visual Aid/ Check List Initiation	▪ Initiate and provide the Control Plan, Process Flow, Work Instruction and Visual Aid for production operator. ▪ Send to customer review	Maintenance/ Process/ Product/ Test/ Failure Analysis/ Quality Engineer , OEM	Between transferring process	DCC	Control Plan, Process Flow, Work Instruction, Visual Aid	▪ If there is any query or need more information, shall feedback or ask it from customer. ▪ If WI is not correct, shall revise and response with customer	▪ Team awareness ▪ Time usage ▪ Customer requirement
10	In-House Training and Examination	▪ Engineer shall train the production operator per Process Flow and Work Instruction ▪ Mfg. Supervisor lets production operators test both theory and on-the-job training. ▪ Mfg. Supervisor keeps operator training record.	Process/ Product/ Test/ Failure Analysis/ Quality Engineer , Production operator, Training center	Between transferring process	Control Plan, Process Flow, Work Instruction, Visual Aid	Knowledge / and know-how of production operator	▪ If there is any query, production operator shall ask it from engineer or Mfg supervisor. ▪ If Production operator does not pass testing for the theory or practice, she must be re-train and retest.	▪ Team awareness ▪ Operator knowledge

No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
11	NPI Production/ Technology Qualification	■ ME shall conduct equipment verification and qualification ■ PE shall conduct product and process verification and qualification ■ QE shall conduct the audit by follow the 5M+1E rule ■ Mfg. Supervisor advises the implementation of process control and perform the Corrective Action (CA) in case of discrepancy was found in the production area ■ Production operator performs per work instruction ■ Engineer monitor for the production build ■ QC Staff/ Assessor performs the audit	Maintenance/ Process/ Product/ Test/ Failure Analysis/ Quality Engineer , Mfg. Supervisor, Production Operator, Quality Control Staff/ Assessor	Between Production/ Technology Qualification	N/A	Qualification report, GR&R, Audit report	■ If there is any discrepancy found in the production area, QC staff/ Assessor shall issue DAR.	■ Time usage ■ Customer requirement
12	Delivery	■ Follow up on schedule of deliveries of modules in order to meet 1st order ■ Update the shipment plan ■ Customer verify the qualification unit	Planner , OEM	Follow the product plan	Shipment plan, Oracle data base	Updated shipment plan, Shipment to customer	■ If any problems occur, the CA and PA will be taken by using error-proofing.	■ Delivery cost ■ Time usage (per Shipment schedule)

No	Method	Action item	Responsibility	Time line (When)	Media (How)	Output	Problem solving & disposition	KPI
13	First Article Report Implementation and Approval	■ Complete the FA report and send customer to approve	Engineering team, OEM	After completing the production build	Email, DCC	FA report	■ If customer do not approve, shall take CA, revise FA report and response with customer.	■ Time usage

9.2.3 Product/ Technology Transfer Check List

This Product/ Technology Transfer Check List help to check the product/ technology transfer readiness.

Project information	Last Updated	
	Product Name	
	Product Family	
	Product Code (s)	
	Build Type	
	Project Kick-off Meeting Date	
	Pilot Run Target Date	
	Quantity	

Project Team	Customer Business Unit	
	Customer Project Lead	
	EMS Project leader	
	EMS Debug Team Lead	
	EMS Test Engineering	
	EMS Quality	
	EMS Maintenance	
	EMS Process	
	EMS Buyer	
	EMS Planner	
	EMS Mfg.	
	Other:	
	Other:	
	Other:	

	Function	Ownership	Executive Summary/ Status	Completion %
Project Status	Product/ Technology Transfer Plan			
	Material Management Plan			
	Manufacturing Plan			
	Quality Plan			
	Other:			
	Other:			
	Other:			

Requirements				Last Update : DDMMYY	Status		Count Cases
						Open	0
						Closed	0

No.	Requirement Description & Lead time	Open Date	% of Completion	Owner	Due Date	Status	Remarks / Comments / Reasons / Exceptions
1	Quality control plan and Flow Chart						
2	Sub-supplier management plan						
3	FMEA						
4	Completeness of WI/VA						
5	Process Audit and Environment audit						
6	GR&R						
7	Capability study						
8	Quality plan						
9	Production manager report the manpower allocation						
10	Training plan to operators						
11	Layout plan and standard time calculation						
12	Tooling & equipment schedule						
13	ECR/ECO handling procedure and cost control process						
14	Packing requirement (domestic and export),						
15	Golden sample handling						
16	Process qualification requirement						
17	Production documents, including process flow-chart, WI (Working Instruction, or MI Manufacturing Instruction), Test Instruction, Final inspection instruction, and packing design and instruction						
18	Equipment Spares Management						
19	Equipment Calibration Management						

Requirements				Last Update : DDMMYY	Status		Count Cases
						Open	0
						Closed	0

No.	Requirement Description & Lead time	Open Date	% of Completion	Owner	Due Date	Status	Remarks / Comments / Reasons / Exceptions
20	Special control build						
21	Product qualification requirement						
22	Purchasing plan and delivery plan (if consigned material). Make sure no material shortage						
23	Supply chain management: the focus is on procurement management and component coding (or BOM coding). Material team should review the BOM and check out which ones are critical components. The critical component mainly means supplier-controlled market and/or high-value unique component						
24	AVL and BOM. In most cases, the NPI BOM is a dummy one. Project assistant should have unique product number and input this number into all relevant systems						
25	BOM cost for OEM design item						
26	Scrapped management						
27	Yielding rate agreement						
28	Training kits support						
29	Process validation materials support						
30	Product qualification materials support						
31	Alpha build materials support						
32	Special epoxy or solder required						
33	Other:						